

Calendar No. 105

105TH CONGRESS  
1ST Session

**S. 830**

[Report No. 105-43]

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

JULY 1, 1997

Reported under authority of the order of the Senate of  
June 27, 1997, with an amendment

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IN THE SENATE OF THE UNITED STATES

JUNE 5, 1997

Mr. JEFFORDS (for himself, Mr. DODD, Mr. COATS, Ms. MIKULSKI, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

JULY 1, 1997

Reported under authority of the order of the Senate of June 27, 1997, by  
Mr. JEFFORDS, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Food and Drug Ad-  
3 ministration Modernization and Accountability Act of  
4 1997”.

5 **SEC. 2. TABLE OF CONTENTS.**

6       The table of contents for this Act is as follows:

Sec. 1. Short title.  
Sec. 2. Table of contents.  
Sec. 3. References.

**TITLE I—IMPROVING PATIENT ACCESS**

Sec. 101. Mission of the Food and Drug Administration.  
Sec. 102. Expedited access to investigational therapies.  
Sec. 103. Expanded humanitarian use of devices.

**TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES**

Sec. 201. Interagency collaboration.  
Sec. 202. Sense of the committee regarding mutual recognition agreements and  
global harmonization efforts.  
Sec. 203. Contracts for expert review.  
Sec. 204. Accredited-party reviews.  
Sec. 205. Device performance standards.

**TITLE III—IMPROVING COLLABORATION AND COMMUNICATION**

Sec. 301. Collaborative determinations of device data requirements.  
Sec. 302. Collaborative review process.

**TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES**

Sec. 401. Policy statements.  
Sec. 402. Product classification.  
Sec. 403. Use of data relating to premarket approval.  
Sec. 404. Consideration of labeling claims for product review.  
Sec. 405. Definition of a day for purposes of product review.  
Sec. 406. Certainty of review timeframes.  
Sec. 407. Limitations on initial classification determinations.  
Sec. 408. Clarification with respect to a general use and specific use of a de-  
vice.  
Sec. 409. Clarification of the number of required clinical investigations for ap-  
proval.  
Sec. 410. Prohibited acts.

**TITLE V—IMPROVING ACCOUNTABILITY**

Sec. 501. Agency plan for statutory compliance and annual report.

**TITLE VI—INCREASING RESOURCES BY SETTING PRIORITIES**

Sec. 601. Minor modifications.  
 Sec. 602. Environmental impact review.  
 Sec. 603. Exemption of certain class devices from premarket notification requirement.  
 Sec. 604. Review of class I and class II devices.  
 Sec. 605. Evaluation of automatic class III designation.  
 Sec. 606. Secretary's discretion to track devices.  
 Sec. 607. Secretary's discretion to conduct postmarket surveillance.  
 Sec. 608. Reporting.  
 Sec. 609. Pilot and small-scale manufacture.  
 Sec. 610. Requirements for radiopharmaceuticals.  
 Sec. 611. Modernization of regulation of biological products.  
 Sec. 612. Supplemental new drug applications.  
 Sec. 613. Health care economic information.  
 Sec. 614. Expediting study and approval of fast track drugs.  
 Sec. 615. Manufacturing changes for drugs and biologics.  
 Sec. 616. Data requirements for drugs and biologics.  
 Sec. 617. Food contact substances.  
 Sec. 618. Health claims of food products.  
 Sec. 619. Pediatric studies marketing exclusivity.

#### TITLE VII—FEES RELATING TO DRUGS

Sec. 701. Short title.  
 Sec. 702. Findings.  
 Sec. 703. Definitions.  
 Sec. 704. Authority to assess and use drug fees.  
 Sec. 705. Annual reports.  
 Sec. 706. Effective date.  
 Sec. 707. Termination of effectiveness.

#### TITLE VIII—MISCELLANEOUS

Sec. 801. Registration of foreign establishments.  
 Sec. 802. Elimination of certain labeling requirements.  
 Sec. 803. Clarification of seizure authority.  
 Sec. 804. Intramural research training award program.  
 Sec. 805. Enforcement authority for special controls.  
 Sec. 806. Device samples.  
 Sec. 807. Interstate commerce.

### 1 **SEC. 3. REFERENCES.**

2       Except as otherwise expressly provided, wherever in  
 3 this Act an amendment or repeal is expressed in terms  
 4 of an amendment to, or repeal of, a section or other provi-  
 5 sion, the reference shall be considered to be made to a  
 6 section or other provision of the Federal Food, Drug, and  
 7 Cosmetic Act (21 U.S.C. 321 et seq.).

1 **TITLE I—IMPROVING PATIENT**  
 2 **ACCESS**

3 **SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRA-**  
 4 **TION.**

5 Section 903 (21 U.S.C. 393) is amended—

6 (1) by redesignating subsections (b) and (c) as  
 7 subsections (c) and (d), respectively; and

8 (2) by adding after subsection (a) the following:

9 “(b) MISSION.—

10 “(1) IN GENERAL.—The Food and Drug Ad-  
 11 ministration shall protect the public health by ensur-  
 12 ing that—

13 “(A) foods are safe, wholesome, and sani-  
 14 tary;

15 “(B) human and veterinary drugs are safe  
 16 and effective;

17 “(C) there is reasonable assurance of safe-  
 18 ty and effectiveness of devices intended for  
 19 human use;

20 “(D) cosmetics are safe; and

21 “(E) public health and safety are protected  
 22 from electronic product radiation.

23 “(2) SPECIAL RULES.—The Food and Drug  
 24 Administration shall promptly and efficiently review  
 25 clinical research and take appropriate action on the

1 marketing of regulated products in a manner that  
 2 does not unduly impede innovation or product avail-  
 3 ability. The Food and Drug Administration shall  
 4 participate with other countries to reduce the burden  
 5 of regulation, to harmonize regulatory requirements,  
 6 and to achieve appropriate reciprocal arrange-  
 7 ments.”.

8 **SEC. 102. EXPEDITED ACCESS TO INVESTIGATIONAL**  
 9 **THERAPIES.**

10 Chapter V (21 U.S.C. 351 et seq.) is amended by  
 11 adding at the end the following:

12 “SUBCHAPTER D—UNAPPROVED THERAPIES AND  
 13 DIAGNOSTICS

14 **“SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERA-**  
 15 **PIES AND DIAGNOSTICS.**

16 “(a) IN GENERAL.—Any person, acting through a  
 17 medical practitioner licensed in accordance with State law,  
 18 may request from a manufacturer or distributor, and any  
 19 manufacturer or distributor may provide to a person after  
 20 compliance with the provisions of this section, an inves-  
 21 tigational drug (including a biological product) or inves-  
 22 tigational device for the diagnosis, monitoring, or treat-  
 23 ment of a serious disease or condition, or any other disease  
 24 or condition designated by the Secretary as appropriate  
 25 for expanded access under this section if—

1           “(1) the licensed medical practitioner deter-  
2           mines that the person has no comparable or satisfac-  
3           tory alternative therapy available to diagnose, mon-  
4           itor, or treat the disease or condition involved;

5           “(2) the licensed medical practioner determines  
6           that the risk to the person from the investigational  
7           drug or investigational device is not greater than the  
8           risk from the disease or condition;

9           “(3) the Secretary determines that an exemp-  
10          tion for the investigational drug or investigational  
11          device is in effect under a regulation promulgated  
12          pursuant to section 505(i) or 520(g) and the spon-  
13          sor of the drug or device and investigators comply  
14          with such regulation;

15          “(4) the Secretary determines that the manu-  
16          facturer of the investigational drug or investigational  
17          device is actively pursuing marketing approval with  
18          due diligence; and

19          “(5) expanded access will not interfere with  
20          adequate enrollment of patients by the investigator  
21          in the ongoing clinical investigation authorized under  
22          section 505(i) or 520(g).

23          “(b) PROTOCOLS.—A manufacturer or distributor  
24          may submit to the Secretary 1 or more expanded access  
25          protocols covering expanded access use of a drug or device

1 described in subsection (a). The protocols shall be subject  
 2 to the provisions of section 505(i) or 520(g) and may in-  
 3 clude any form of use of the drug or device outside a clini-  
 4 cal investigation, prior to approval of the drug or device  
 5 for marketing, including protocols for treatment use,  
 6 emergency use, or uncontrolled trials, and single patient  
 7 protocols.

8 “(e) NOTIFICATION OF AVAILABILITY.—The Sec-  
 9 retary shall inform national, State, and local medical asso-  
 10 ciations and societies, voluntary health associations, and  
 11 other appropriate persons about the availability of an in-  
 12 vestigational drug or investigational device under ex-  
 13 panded access protocols submitted under this section.”.

14 (d) TERMINATION.—FDA may at any time terminate  
 15 expanded access under subsection (a) if the requirements  
 16 under this section are no longer met.

17 **SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.**

18 Section 520(m) (21 U.S.C. 360j(m)) is amended—

19 (1) in paragraph (2), by adding at the end the  
 20 following flush sentences:

21 “The request shall be in the form of an application sub-  
 22 mitted to the Secretary. Not later than 60 days after the  
 23 date of the receipt of the application, the Secretary shall  
 24 issue an order approving or denying the application.”;



1           (2) in paragraph (4)(B), by inserting after  
 2       “(2)(A)” the following: “, unless a physician deter-  
 3       mines that waiting for such an approval from an in-  
 4       stitutional review committee will cause harm or  
 5       death to a patient, and after making a good faith ef-  
 6       fort, the physician does not receive a timely response  
 7       from an institutional review committee on the physi-  
 8       cian’s request for approval to use the device.

9           (3) by striking paragraph (5) and inserting the  
 10       following:

11       “(5) The Secretary may require a person granted an  
 12       exemption under paragraph (2) to demonstrate continued  
 13       compliance with the requirements of this subsection if the  
 14       Secretary believes such demonstration to be necessary to  
 15       protect the public health or if the Secretary has reason  
 16       to believe that the criteria for the exemption are no longer  
 17       met. Nothing in this section shall be construed to prevent  
 18       the Secretary from using any of the controls authorized  
 19       by or under section 501, 502, 510, 516, 518, 519, or 520,  
 20       any combination of such controls, or any of the special  
 21       controls established under section 513(a)(1)(B), in con-  
 22       nection with a device for which an exemption has been  
 23       granted under paragraph (2).”.

1   **TITLE II—INCREASING ACCESS**  
 2   **TO EXPERTISE AND RESOURCES**

3   **SEC. 201. INTERAGENCY COLLABORATION.**

4       Section 903(b) (21 U.S.C. 393(b)) is amended by  
 5 adding at the end the following:

6           “(3) INTERAGENCY COLLABORATION.—The  
 7 Secretary shall implement programs and policies  
 8 that will foster collaboration between the Adminis-  
 9 tration, the National Institutes of Health, and other  
 10 science-based Federal agencies, to enhance the sci-  
 11 entific and technical expertise available to the Sec-  
 12 retary in the conduct of the Secretary’s duties with  
 13 respect to the development, clinical investigation,  
 14 evaluation, and postmarket monitoring of emerging  
 15 medical therapies, including complementary thera-  
 16 pies, and advances in nutrition and food science.”.

17   **SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL**  
 18           **RECOGNITION AGREEMENTS AND GLOBAL**  
 19           **HARMONIZATION EFFORTS.**

20       It is the sense of the Committee that—

21           (1) the Secretary of Health and Human Serv-  
 22 ices, in consultation with the Secretary of Com-  
 23 merce, should move toward the acceptance of mutual  
 24 recognition agreements relating to the regulation of  
 25 drugs, biological products, devices, foods, food addi-

tives, and color additives, and the regulation of good manufacturing practices, reached between the European Union and the United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

**SEC. 203. CONTRACTS FOR EXPERT REVIEW.**

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

**“SEC. 906. CONTRACTS FOR EXPERT REVIEW.**

**“(a) IN GENERAL.—**

**“(1) AUTHORITY.—**The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Sec-

1       retary on part or all of any application or submis-  
2       sion (including a petition, notification, and any other  
3       similar form of request) made under this Act for the  
4       approval of an article or made under section 351(a)  
5       of the Public Health Service Act (42 U.S.C. 262(a))  
6       with respect to a biological product. Any such con-  
7       tract shall be subject to the requirements of section  
8       708 relating to the confidentiality of information.

9           ~~“(2) INCREASED EFFICIENCY AND EXPERTISE~~  
10       ~~THROUGH CONTRACTS.—~~The Secretary shall use the  
11       authority granted in paragraph (1) whenever the  
12       Secretary determines that a contract described in  
13       paragraph (1) will improve the timeliness or quality  
14       of the review of an application or submission de-  
15       scribed in paragraph (1). Such improvement may in-  
16       clude providing the Secretary increased scientific or  
17       technical expertise that is necessary to review or  
18       evaluate new therapies and technologies.

19       ~~“(b) REVIEW OF EXPERT’S EVALUATION.—~~

20           ~~“(1) IN GENERAL.—~~Subject to paragraph (2),  
21       the official of the Food and Drug Administration re-  
22       sponsible for any matter for which expert review is  
23       used pursuant to subsection (a) shall review the rec-  
24       ommendations of the organization or individual who  
25       conducted the expert review and shall make a final

1 decision regarding the matter within 60 days after  
 2 receiving the recommendations.

3 ~~“(2) LIMITATION.—A final decision under para-~~  
 4 ~~graph (1) shall be made within the applicable pre-~~  
 5 ~~scribed time period for review of the matter as set~~  
 6 ~~forth in this Act.~~

7 ~~“(3) AUTHORITY OF SECRETARY.—Notwith-~~  
 8 ~~standing subsection (a), the Secretary shall retain~~  
 9 ~~full authority to make determinations with respect to~~  
 10 ~~the approval or disapproval of an article under this~~  
 11 ~~Act, or the classification of an article as a device~~  
 12 ~~under section 513(f)(1).”.~~

13 **SEC. 204. ACCREDITED-PARTY REVIEWS.**

14 Subchapter A of chapter V (21 U.S.C. 351 et seq.)  
 15 is amended by adding at the end the following:

16 **“SEC. 523. ACCREDITED-PARTY PARTICIPATION.**

17 ~~“(a) ACCREDITATION.—~~

18 ~~“(1) IN GENERAL.—Not later than 1 year after~~  
 19 ~~the date of enactment of this section, the Secretary~~  
 20 ~~shall accredit persons, including any entity or indi-~~  
 21 ~~vidual who is not an employee of United States Gov-~~  
 22 ~~ernment, to review and make recommendations re-~~  
 23 ~~garding submissions made to the Secretary under~~  
 24 ~~section 510(k) except that this paragraph does not~~  
 25 ~~apply to submissions for devices that are—~~

1                   ~~“(A) life-supporting;~~  
 2                   ~~“(B) life sustaining; or~~  
 3                   ~~“(C) intended for implantation in the~~  
 4                   ~~human body for a period of over 1 year.~~

5                   ~~“(2) SPECIAL RULE.—The Secretary shall have~~  
 6                   ~~the discretion to accredit persons, including any en-~~  
 7                   ~~tity or individual who is not an employee of the~~  
 8                   ~~United States Government, to review and make rec-~~  
 9                   ~~ommendations regarding devices described in sub-~~  
 10                   ~~paragraphs (A) through (C) of paragraph (1) or de-~~  
 11                   ~~vices subject to premarket approval under section~~  
 12                   ~~515.~~

13                   ~~“(b) ACCREDITATION.—Within 180 days after the~~  
 14                   ~~date of enactment of this section, the Secretary shall adopt~~  
 15                   ~~methods of accreditation that ensure that persons who~~  
 16                   ~~conduct reviews and make recommendations under this~~  
 17                   ~~section are qualified, properly trained, knowledgeable~~  
 18                   ~~about handling confidential documents and information,~~  
 19                   ~~and free of conflicts of interest. The Secretary shall pub-~~  
 20                   ~~lish the methods of accreditation in the Federal Register~~  
 21                   ~~on the adoption of the methods.~~

22                   ~~“(c) WITHDRAWAL OF ACCREDITATION.—The Sec-~~  
 23                   ~~retary may suspend or withdraw the accreditation of any~~  
 24                   ~~person accredited under this section, after providing notice~~  
 25                   ~~and an opportunity for an informal hearing, if such person~~

1 acts in a manner that is substantially not in compliance  
2 with the requirements established by the Secretary, includ-  
3 ing the failure to avoid conflicts of interest, the failure  
4 to protect confidentiality of information, or the failure to  
5 competently review premarket submissions for devices.

6 “(d) SELECTION AND COMPENSATION.—A person  
7 who intends to submit a premarket submission for a device  
8 to the Secretary under subsection (a) shall have the option  
9 to select an accredited person to review such submission.  
10 Upon the request of a person intending to make a pre-  
11 market submission for a device, the Secretary shall iden-  
12 tify for the person no less than 2 accredited persons from  
13 whom the selection may be made. Compensation for an  
14 accredited person shall be determined by agreement be-  
15 tween the accredited person and the person who engages  
16 the services of the accredited person and shall be paid by  
17 the person who engages such services.

18 “(e) REVIEW BY SECRETARY.—The Secretary shall  
19 require an accredited person, upon recommending a classi-  
20 fication of a device or approval or disapproval of an appli-  
21 cation for a device, to report to the Secretary the reasons  
22 of the accredited person for such recommendation of clas-  
23 sification or approval or disapproval. For devices reviewed  
24 and initially classified under section 513(f)(1) and subject  
25 to a report under section 510(k), the Secretary shall have

1 not more than 30 days to review the submission. For ap-  
 2 plications submitted under section 515(e)(1), the Sec-  
 3 retary shall have not more than 60 days to review the ap-  
 4 plication. The Secretary may change the classification  
 5 under section 513(f)(1), or the approval or disapproval of  
 6 the application under section 515(d), that is recommended  
 7 by the accredited person, and in such case shall notify in  
 8 writing the person making the submission of the detailed  
 9 reasons for the change.

10 “(f) DURATION.—The authority provided by this sec-  
 11 tion terminates—

12 “(1) 5 years after the date on which the Sec-  
 13 retary notifies Congress that at least 2 persons ac-  
 14 credited under subsection (b) are available to review  
 15 devices in each of at least 70 percent of generic  
 16 types of devices required for review under subsection  
 17 (a); or

18 “(2) 4 years after the date on which the Sec-  
 19 retary notifies Congress that at least 35 percent of  
 20 the devices required for review under subsection (a)  
 21 that were the subject of final action by the Secretary  
 22 in the fiscal year preceding the date on which the  
 23 Secretary notifies the Congress were reviewed by the  
 24 Secretary under subsection (e);  
 25 whichever occurs first.



1       “(g) REPORT.—

2               “(1) IN GENERAL.—Not later than 1 year after  
3       the date of enactment of this section, the Secretary  
4       shall contract with an independent research organi-  
5       zation to prepare and submit to the Secretary a  
6       written report examining the use of accredited per-  
7       sons under this section. The Secretary shall submit  
8       the report to Congress not later than 6 months prior  
9       to the conclusion of the applicable period described  
10      in subsection (f).

11              “(2) CONTENTS.—The report by the independ-  
12      ent research organization described in paragraph (1)  
13      shall identify the benefits or detriments to public  
14      and patient health of using accredited persons to  
15      conduct such reviews, and shall summarize all rel-  
16      evant data, including data on the review of accred-  
17      ited persons (including review times, recommenda-  
18      tions, and compensation), and data on the review of  
19      the Secretary (including review times, changes, and  
20      reasons for changes).”.

21   **SEC. 205. DEVICE PERFORMANCE STANDARDS.**

22              (a) ALTERNATIVE PROCEDURE.—Section 514 (21  
23   U.S.C. 360d) is amended by adding at the end the follow-  
24   ing:

1                   “RECOGNITION OF A STANDARD

2           “(e)(1)(A) In addition to establishing performance  
3 standards under this section, the Secretary may, by publi-  
4 cation in the Federal Register, recognize all or part of a  
5 performance standard established by a nationally or inter-  
6 nationally recognized standard development organization  
7 for which a person may submit a declaration of conformity  
8 in order to meet premarket submission requirements or  
9 other requirements under this Act to which such standards  
10 are applicable.

11          “(B) If a person elects to use a performance standard  
12 recognized by the Secretary under subparagraph (A) to  
13 meet the requirements described in subparagraph (A), the  
14 person shall provide a declaration of conformity to the  
15 Secretary that certifies that the device is in conformity  
16 with such standard. A person may elect to use data, or  
17 information, other than data required by a standard recog-  
18 nized under subparagraph (A) to fulfill or satisfy any re-  
19 quirement under this Act.

20          “(2) The Secretary may withdraw such recognition  
21 of a performance standard through publication of a notice  
22 in the Federal Register that the Secretary will no longer  
23 recognize the standard, if the Secretary determines that  
24 the standard is no longer appropriate for meeting the re-  
25 quirements under the Act.

1       “(3)(A) Subject to subparagraph (B), the Secretary  
 2 shall accept a declaration of conformity that a device is  
 3 in conformity with a standard recognized under paragraph  
 4 (1) unless, the Secretary finds—

5           “(i) that the data or information submitted to  
 6 support such declaration does not demonstrate that  
 7 the device is in conformity with the standard identi-  
 8 fied in the declaration of conformity; or

9           “(ii) that the standard identified in the declara-  
 10 tion of conformity is not applicable to the particular  
 11 device under review.

12       “(B) The Secretary may request, at any time, the  
 13 data or information relied on by the person to make a  
 14 declaration of conformity with respect to a standard recog-  
 15 nized under paragraph (1).

16       “(C) A person relying on a declaration of conformity  
 17 with respect to a standard recognized under paragraph (1)  
 18 shall maintain the data and information demonstrating  
 19 conformity of the device to the standard for a period of  
 20 2 years after the date of the Secretary’s classification or  
 21 approval of the device or a time equal to the expected de-  
 22 sign life of a device, whichever is longer.”.

23       (b) SECTION 301.—Section 301 (21 U.S.C. 331) is  
 24 amended by adding at the end the following:

1       ~~“(x) The falsification of a declaration of conformity~~  
 2       ~~under subsection (e)(3) of section 514 or the failure or~~  
 3       ~~refusal to provide data or information requested by the~~  
 4       ~~Secretary under such subsection.”.~~

5       ~~(e) SECTION 501.—Section 501(e) (21 U.S.C.~~  
 6       ~~351(e)) is amended—~~

7               ~~(1) by striking “(e)” and inserting “(e)(1)”;~~  
 8       ~~and~~

9               ~~(2) by inserting at the end the following:~~

10       ~~“(2) If it is, purports to be, or is represented as, a~~  
 11       ~~device that is declared to be in conformity with any per-~~  
 12       ~~formance standard recognized under section 514(e) unless~~  
 13       ~~such device is in all respects in conformity with such~~  
 14       ~~standard.”.~~

## 15   **TITLE    III—IMPROVING    COL-** 16       **LABORATION   AND   COMMU-** 17       **NICATION**

### 18   **SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE** 19       **DATA REQUIREMENTS.**

20       Section 513(a)(3) (21 U.S.C. 360e(a)(3)) is amended  
 21       by adding at the end the following:

22       ~~“(C)(i) The Secretary, upon the written request of~~  
 23       ~~any person intending to submit an application under sec-~~  
 24       ~~tion 515, shall meet with such person to determine the~~  
 25       ~~type of valid scientific evidence within the meaning of sub-~~

1 paragraphs (A) and (B) that will be necessary to dem-  
 2 onstrate the effectiveness of a device for the conditions  
 3 of use proposed by such person; to support an approval  
 4 of an application. Within 30 days after such meeting, the  
 5 Secretary shall specify in writing the type of valid sci-  
 6 entific evidence that will provide a reasonable assurance  
 7 that a device is effective under the conditions of use pro-  
 8 posed by such person. Any clinical data, including 1 or  
 9 more well-controlled investigations, specified in writing by  
 10 the Secretary for demonstrating a reasonable assurance  
 11 of device effectiveness shall be specified as a result of a  
 12 determination by the Secretary that such data are nec-  
 13 essary to establish device effectiveness and that no other  
 14 less burdensome means of evaluating device effectiveness  
 15 are available which would have a reasonable likelihood of  
 16 resulting in an approval.

17 “(ii) The determination of the Secretary with respect  
 18 to the specification of valid scientific evidence under clause  
 19 (i) shall be binding upon the Secretary, unless—

20 “(I) such determination by the Secretary would  
 21 be contrary to the public health; or

22 “(II) based on new information obtained by the  
 23 Secretary prior to the approval of an application for  
 24 an investigational device exemption under section

1       520(g), the Secretary finds that such determination  
 2       is scientifically inappropriate.”.

3       **SEC. 302. COLLABORATIVE REVIEW PROCESS.**

4       Section 515(d) (21 U.S.C. 360e(d)) is amended—

5           (1) in paragraph (1)(A), by striking “paragraph  
 6       (2) of this subsection” each place it appears and in-  
 7       serting “paragraph (4)”;

8           (2) by redesignating paragraphs (2) and (3) as  
 9       paragraphs (4) and (5), respectively; and

10          (3) by inserting after paragraph (1) the follow-  
 11       ing:

12       “(2)(A) The Secretary shall meet with an applicant  
 13       not later than 100 days after the receipt of an application  
 14       that has been filed as complete under subsection (c) to  
 15       discuss the review status of the application. If the applica-  
 16       tion does not appear in a form that would require an ap-  
 17       proval under this subsection, the Secretary shall in writ-  
 18       ing, and prior to the meeting, provide to the applicant a  
 19       description of any deficiencies in the application identified  
 20       by the Secretary and identify the information (other than  
 21       information the Secretary needs to making a finding  
 22       under paragraph (4)(C)) that is required to bring the ap-  
 23       plication into a form that would require an approval. The  
 24       Secretary and the applicant may, by mutual consent, es-

1 establish a different schedule for a meeting required under  
 2 this paragraph.

3 “(B) The Secretary shall notify the applicant imme-  
 4 diately of any deficiency identified in the application that  
 5 was not described as a deficiency in the written description  
 6 provided by the Secretary under subparagraph (A).”.

## 7 **TITLE IV—IMPROVING CER-** 8 **TAINTY AND CLARITY OF** 9 **RULES**

### 10 **SEC. 401. POLICY STATEMENTS.**

11 Section 701(a) (21 U.S.C. 371(a)) is amended—

12 (1) by striking “(a) The” and inserting “(a)(1)  
 13 The”; and

14 (2) by adding at the end the following:

15 “(2) Not later than February 27, 1999, the Sec-  
 16 retary, after evaluating the effectiveness of the Good Guid-  
 17 ance Practices document published in the Federal Register  
 18 at 62 Fed. Reg. 8961, shall promulgate as a regulation  
 19 in the Federal Register the policies and procedures of the  
 20 Food and Drug Administration for the development, issu-  
 21 ance, and use of guidance documents.”.

### 22 **SEC. 402. PRODUCT CLASSIFICATION.**

23 Chapter VII (21 U.S.C. 371 et seq.) is amended by  
 24 adding at the end the following:

1       “SUBCHAPTER D—REVIEW OF APPLICATIONS AND  
2               ENVIRONMENTAL IMPACT REVIEWS

3       “SEC. 741. CONTENT AND REVIEW OF AN APPLICATION OR  
4               SUBMISSION.

5       “(a) CLASSIFICATION OF A PRODUCT.—

6               “(1) REQUEST.—A person who submits an ap-  
7       plication or submission (including a petition, notifi-  
8       cation, and any other similar form of request) under  
9       this Act, may submit a request to the Secretary re-  
10      specting the classification of an article (including an  
11      article that is a combination product subject to sec-  
12      tion 503(g)) as a drug, biological product, or device,  
13      or respecting the component of the Food and Drug  
14      Administration that will regulate the article. In sub-  
15      mitting the request, the person shall recommend a  
16      classification for the article, or the component that  
17      should regulate the article, as appropriate.

18              “(2) STATEMENT.—Not later than 60 days  
19      after the receipt of the request described in para-  
20      graph (1), the Secretary shall determine the classi-  
21      fication of the article or the component of the Food  
22      and Drug Administration that will regulate the arti-  
23      cle and shall provide to the person a written state-  
24      ment that identifies the classification of the article  
25      or the component of the Food and Drug Administra-



tion that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

“(3) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in paragraph (2), the recommendation made by the person under paragraph (1) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.”.

**SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.**

Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

“(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6

1 years after the application has been approved by the Sec-  
 2 retary, for use by the Secretary in—

3 “(i) approving devices;

4 “(ii) determining whether a product develop-  
 5 ment protocol has been completed, under section  
 6 515;

7 “(iii) establishing a performance standard or  
 8 special control under section 514; and

9 “(iv) classifying or reclassifying devices under  
 10 section 513 and subsection (1)(2).

11 “(B) The publicly available detailed summaries of in-  
 12 formation respecting the safety and effectiveness of de-  
 13 vices required by paragraph (1)(A) shall be available for  
 14 use by the Secretary as the evidentiary basis for the regu-  
 15 latory action described in subparagraph (A).”.

16 **SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR**  
 17 **PRODUCT REVIEW.**

18 (a) **PREMARKET APPROVAL.**—Section 515(d)(1)(A)  
 19 (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the  
 20 end the following flush sentences:

21 “In making the determination whether to approve or deny  
 22 an application, the Secretary shall rely on the conditions  
 23 of use proposed in the labeling of a device as the basis  
 24 for determining whether or not there is a reasonable as-  
 25 surance of safety and effectiveness. If, based on a fair

1 evaluation of all material facts, the proposed labeling is  
 2 neither false nor misleading in any particular, the Sec-  
 3 retary, in making the determination, shall not consider  
 4 conditions of use not included in the proposed labeling.”.

5 (b) **PREMARKET NOTIFICATION.**—Section 513(i)(1)  
 6 ~~(21 U.S.C. 360e(i)(1))~~ is amended by adding at the end  
 7 the following:

8 “(C) Whenever the Secretary requests information to  
 9 demonstrate that the devices with differing technological  
 10 characteristics are substantially equivalent, the Secretary  
 11 shall only request information that is necessary to make  
 12 a substantial equivalence determination. In making such  
 13 a request, the Secretary shall consider the least burden-  
 14 some means of demonstrating substantial equivalence and  
 15 shall request information accordingly.

16 “(D) Any determinations of substantial equivalence  
 17 by the Secretary shall be based upon the intended uses  
 18 proposed in labeling submitted in a report under section  
 19 510(k).”.

20 **SEC. 405. DEFINITION OF A DAY FOR PURPOSES OF PROD-**  
 21 **UCT REVIEW.**

22 Section 201 ~~(21 U.S.C. 321)~~ is amended by adding  
 23 at the end the following:

24 “(ii) In any provision relating to a review of any ap-  
 25 plication or submission (including a petition, notification,

1 and any other similar form of request); made under this  
 2 Act with respect to an article that is a new drug, device,  
 3 biological product, new animal drug, an animal feed bear-  
 4 ing or containing a new animal drug, color additive, or  
 5 food additive, that is submitted to the Secretary to obtain  
 6 marketing approval, to obtain classification of a device  
 7 under section 513(f)(1), or to establish or clarify the regu-  
 8 latory status of the article, the term ‘day’ means a cal-  
 9 endar day in which the Secretary has responsibility to re-  
 10 view such an application or submission (excluding any cal-  
 11 endar day between the date of receipt, by the person sub-  
 12 mitting the application or submission, of a written commu-  
 13 nication from the Secretary setting forth the action of the  
 14 Secretary on the application or submission and the date  
 15 of receipt by the Secretary of the written response of the  
 16 person to the action).”.

17 **SEC. 406. CERTAINTY OF REVIEW TIMEFRAMES.**

18 (a) **CLARIFICATION ON THE 90-DAY TIMEFRAME FOR**  
 19 **PREMARKET NOTIFICATION REVIEWS.**—Section 510(k)  
 20 (21 U.S.C. 360) is amended by adding at the end the fol-  
 21 lowing flush sentence:  
 22 “The Secretary shall review the notification required by  
 23 this subsection and make a determination under section  
 24 513(f)(1) not later than 90 days after receiving the notifi-  
 25 cation.”.

1       (b) ~~CERTAINTY OF 180-DAY REVIEW TIME~~  
 2 ~~FRAME.~~—Section 515(d) (21 U.S.C. 360e(d)), as amend-  
 3 ed by section 302, is amended by inserting after para-  
 4 graph (2) the following:

5       “(3) The time for the review of an application by the  
 6 Secretary under this subsection shall take not more than  
 7 180 days and such time may not be extended if the appli-  
 8 cation is amended.”.

9       **SEC. 407. LIMITATIONS ON INITIAL CLASSIFICATION DE-**  
 10                                   **TERMINATIONS.**

11       Section 510 (21 U.S.C. 360) is amended by adding  
 12 at the end the following:

13       “(m)(1) The Secretary may not withhold a deter-  
 14 mination of the initial classification of a device under sec-  
 15 tion 513(f)(1) because of a failure to comply with any pro-  
 16 vision of this Act that is unrelated to a substantial equiva-  
 17 lence decision, including a failure to comply with the re-  
 18 quirements relating to good manufacturing practices  
 19 under section 520(f).

20       “(2) Nothing in this provision shall be construed to  
 21 prevent the Secretary from using any of the controls au-  
 22 thorized by or under section 501, 502, 510, 516, 518, 519,  
 23 or 520, or any combination of such controls, or any of  
 24 the special controls established under section 513(a)(1)(B)  
 25 to regulate a marketed device.”.

1 **SEC. 408. CLARIFICATION WITH RESPECT TO A GENERAL**  
 2 **USE AND SPECIFIC USE OF A DEVICE.**

3 Not later than 270 days after the date of enactment  
 4 of this section, the Secretary shall promulgate a final reg-  
 5 ulation specifying the general principles that the Secretary  
 6 will consider in determining when a specific intended use  
 7 of a device is not reasonably included within a general use  
 8 of such device for purposes of a determination of substan-  
 9 tial equivalence under section 513(f)(1) of the Federal  
 10 Food, Drug, and Cosmetic Act (21 U.S.C. 360(f)(1)) :

11 **SEC. 409. CLARIFICATION OF THE NUMBER OF REQUIRED**  
 12 **CLINICAL INVESTIGATIONS FOR APPROVAL.**

13 (a) **DEVICE CLASSES.**—Section 513(a)(3)(A) (21  
 14 U.S.C. 360e(a)(3)(A)) is amended by striking “clinical in-  
 15 vestigations” and inserting “one or more clinical investiga-  
 16 tions”.

17 (b) **NEW DRUGS.**—Section 505(d) (21 U.S.C.  
 18 355(d)) is amended by adding at the end the following:  
 19 “If the Secretary determines that only one investigation  
 20 is required, then the Secretary may require appropriate  
 21 supporting scientific evidence obtained prior to or after  
 22 such investigation. The Secretary shall establish a mecha-  
 23 nism to ensure the fair and consistent application of this  
 24 provision to new drugs”.

25 **SEC. 410. PROHIBITED ACTS.**

26 Section 301(l) (21 U.S.C. 331(l)) is repealed.

# TITLE V—IMPROVING ACCOUNTABILITY

## SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

“(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

“(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, and representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

“(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives for and mechanisms to be used

1 by the Secretary, acting through the Commis-  
2 sioner, including objectives and mechanisms  
3 that—

4 “(i) minimize deaths of, and harm to,  
5 persons who use or may use an article reg-  
6 ulated under this Act;

7 “(ii) maximize the clarity of, and the  
8 availability of information about, the proe-  
9 cess for review of applications and submis-  
10 sions (including petitions, notifications,  
11 and any other similar forms of request)  
12 made under this Act, including information  
13 for potential consumers and patients con-  
14 cerning new products;

15 “(iii) implement all inspection and  
16 postmarket monitoring provisions of this  
17 Act by July 1, 1999;

18 “(iv) ensure access to the scientific  
19 and technical expertise necessary to ensure  
20 compliance by the Secretary with the stat-  
21 utory obligations described in subpara-  
22 graph (A);

23 “(v) establish a schedule to bring the  
24 Administration into full compliance by  
25 July 1, 1999, with the time periods speci-



1           fied in this Act for the review of all appli-  
 2           cations and submissions described in clause  
 3           (ii) and submitted after the date of enact-  
 4           ment of this paragraph; and

5           “~~(vi)~~ reduce backlogs in the review of  
 6           all applications and submissions described  
 7           in clause (ii) for any article with the objec-  
 8           tive of eliminating all backlogs in the re-  
 9           view of the applications and submissions  
 10          by January 1, 2000.

11       ~~“(5) ANNUAL REPORT.—~~

12           ~~“(A) CONTENTS.—~~The Secretary shall pre-  
 13       pare and publish in the Federal Register and  
 14       solicit public comment on an annual report  
 15       that—

16           ~~“(i)~~ provides detailed statistical infor-  
 17       mation on the performance of the Sec-  
 18       retary under the plan described in para-  
 19       graph (4);

20           ~~“(ii)~~ compares such performance of  
 21       the Secretary with the objectives of the  
 22       plan and with the statutory obligations of  
 23       the Secretary;

1 “(iii) analyzes any failure of the Sec-  
 2 retary to achieve any objective of the plan  
 3 or to meet any statutory obligation;

4 “(iv) identifies any regulatory policy  
 5 that has a significant impact on compli-  
 6 ance with any objective of the plan or any  
 7 statutory obligation; and

8 “(v) sets forth any proposed revision  
 9 to any such regulatory policy, or objective  
 10 of the plan that has not been met.

11 “(B) STATISTICAL INFORMATION.—The  
 12 statistical information described in subpara-  
 13 graph (A)(i) shall include a full statistical pres-  
 14 entation relating to all applications and submis-  
 15 sions (including petitions, notifications, and any  
 16 other similar forms of request) made under this  
 17 Act and approved or subject to final action by  
 18 the Secretary during the year covered by the re-  
 19 port. In preparing the statistical presentation,  
 20 the Secretary shall take into account the date  
 21 of—

22 “(i) the submission of any investiga-  
 23 tional application;

24 “(ii) the application of any clinical  
 25 hold;

1           “(iii) the submission of any applica-  
 2           tion or submission (including a petition,  
 3           notification, and any other similar form of  
 4           request) made under this Act for approval  
 5           or clearance;

6           “(iv) the acceptance for filing of any  
 7           application or submission described in  
 8           clause (iii) for approval or clearance;

9           “(v) the occurrence of any  
 10          unapprovable action;

11          “(vi) the occurrence of any approvable  
 12          action; and

13          “(vii) the approval or clearance of any  
 14          application or submission described in  
 15          clause (iii).”.

## 16 **TITLE VI—INCREASING RE-** 17 **SOURCES BY SETTING PRIOR-** 18 **ITIES**

### 19 **SEC. 601. MINOR MODIFICATIONS.**

20          (a) PROCEDURES AND CONDITIONS.—Section 520(g)  
 21          (21 U.S.C. 360j(g)) is amended by adding at the end the  
 22          following:

23          “(6)(A) The Secretary shall, not later than 120 days  
 24          after the date of enactment of this paragraph, by regula-  
 25          tion modify parts 812 and 813 of title 21, Code of Federal

1 Regulations to update the procedures and conditions  
2 under which a device intended for human use may, upon  
3 application by the sponsor of the device, be granted an  
4 exemption from certain requirements under this Act.

5 “(B) The regulation shall permit developmental  
6 changes in devices (including manufacturing changes) in  
7 response to information collected during an investigation  
8 without requiring an additional approval of an application  
9 for an investigational device exemption or the approval of  
10 a supplement to such application, if the sponsor of the  
11 investigation determines, prior to making any changes,  
12 that the changes—

13 “(i) do not affect the scientific soundness of an  
14 investigational plan submitted under paragraph  
15 (3)(A) or the rights, safety, or welfare of the human  
16 subjects involved in the investigation; and

17 “(ii) do not constitute a significant change in  
18 design, or a significant change in basic principles of  
19 operation, of the device.”

20 (b) ACTION ON APPLICATION.—Section 515(d)(1)(B)  
21 (~~21 U.S.C. 360e(d)(1)(B)~~) is amended by adding at the  
22 end the following:

23 “(iii) The Secretary shall accept and review data and  
24 any other information from investigations conducted  
25 under the authority of regulations required by section

1 520(g) to make a determination of whether there is a rea-  
 2 sonable assurance of safety and effectiveness of a device  
 3 subject to a pending application under this section if—

4 “(I) the data or information is derived from in-  
 5 vestigations of an earlier version of the device, the  
 6 device has been modified during or after the inves-  
 7 tigations (but prior to submission of an application  
 8 under section 515(e)) and such a modification of the  
 9 device does not constitute a significant change in the  
 10 design or in the basic principles of operation of the  
 11 device that would invalidate the data or information;  
 12 or

13 “(II) the data or information relates to a device  
 14 approved under this section, is available for use  
 15 under this Act, and is relevant to the design and  
 16 intended use of the device subject to the pending ap-  
 17 plication.”.

18 (c) ACTION ON SUPPLEMENTS.—Section 515(d) (21  
 19 U.S.C. 360e(d)), as amended by section 302, is further  
 20 amended by adding at the end the following:

21 “(6)(A) A supplemental application shall be required  
 22 for any change to a device subject to an approved applica-  
 23 tion under this subsection that affects safety or effective-  
 24 ness, unless such change is a modification in a manufac-  
 25 turing procedure or method of manufacturing and the

1 holder of an approved application submits a written notice  
 2 to the Secretary that describes the change and informs  
 3 the Secretary that the change has been made under the  
 4 requirements of section 520(f).

5 “(B)(i) Subject to clause (ii), in reviewing a supple-  
 6 ment to an approved application for an incremental  
 7 change to the design of a device that affects safety or ef-  
 8 fectiveness, the Secretary shall approve such supplement  
 9 if—

10 “(I) nonclinical data demonstrate that a design  
 11 modification creates the intended additional capac-  
 12 ity, function, or performance of the device; and

13 “(H) clinical data from the approved applica-  
 14 tion and any supplement to the approved application  
 15 provide a reasonable assurance of safety and effec-  
 16 tiveness.

17 “(ii) The Secretary may require, when necessary, ad-  
 18 ditional clinical data to evaluate the design modification  
 19 to provide a reasonable assurance of safety and effective-  
 20 ness.”.

21 **SEC. 602. ENVIRONMENTAL IMPACT REVIEW.**

22 Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 23 section 402, is further amended by adding at the end the  
 24 following:

1 **~~“SEC. 742. ENVIRONMENTAL IMPACT REVIEW.~~**

2       ~~“Notwithstanding any other provision of law, no ac-~~  
 3 ~~tion by the Secretary pursuant to this Act shall be subject~~  
 4 ~~to an environmental assessment, an environmental impact~~  
 5 ~~statement, or other environmental consideration unless the~~  
 6 ~~Secretary demonstrates, in writing—~~

7           ~~“(1) that there is a reasonable probability that~~  
 8       ~~the environmental impact of the action is sufficiently~~  
 9       ~~substantial and within the factors that the Secretary~~  
 10       ~~is authorized to consider under this Act; and~~

11           ~~“(2) that consideration of the environmental~~  
 12       ~~impact will directly affect the decision on the ac-~~  
 13       ~~tion.”.~~

14 **~~SEC. 603. EXEMPTION OF CERTAIN CLASS DEVICES FROM~~**  
 15 **~~PREMARKET NOTIFICATION REQUIREMENT.~~**

16       ~~Section 510 (21 U.S.C. 360) is amended inserting~~  
 17 ~~after subsection (k) the following:~~

18       ~~“(1)(1) Not later than 30 days after the date of enact-~~  
 19 ~~ment of this subsection, the Secretary shall publish in the~~  
 20 ~~Federal Register a list of each type of class II device that~~  
 21 ~~does not require a notification under subsection (k) to pro-~~  
 22 ~~vide reasonable assurance of safety and effectiveness.~~  
 23 ~~Each type of class II device identified by the Secretary~~  
 24 ~~not to require the notification shall be exempt from the~~  
 25 ~~requirement to provide notification under subsection (k)~~

1 as of the date of the publication of the list in the Federal  
2 Register.

3 “(2) Beginning on the date that is 1 day after the  
4 date of the publication of a list under this subsection, any  
5 person may petition the Secretary to exempt a type of  
6 class II device from the notification requirement of sub-  
7 section (k). The Secretary shall publish notice of the peti-  
8 tion in the Federal Register and provide a 30-day period  
9 for public comment. The Secretary shall respond to the  
10 petition within 120 days after the receipt of the petition  
11 and determine whether or not to grant the petition in  
12 whole or in part.”.

13 **SEC. 604. REVIEW OF CLASS I AND CLASS II DEVICES.**

14 (a) EXEMPTION FROM PREMARKET NOTIFICA-  
15 TION.—Section 510(k) (21 U.S.C. 360(k)) is amended by  
16 striking “intended for human use” and inserting “in-  
17 tended for human use (except a device that is classified  
18 into class I under section 513 or 520 unless such device  
19 is intended for a use which is of substantial importance  
20 in preventing impairment of human health, or presents a  
21 potential unreasonable risk of illness or injury, or a device  
22 that is classified into class II under section 513 or 520  
23 and is exempt from the requirements of this subsection  
24 under subsection (l))”.



1 **SEC. 605. EVALUATION OF AUTOMATIC CLASS III DESIGNA-**  
2 **TION.**

3 Section 513(f) (21 U.S.C. 360e(f)) is amended—

4 (1) in paragraph (1) in the last sentence, by  
5 striking “paragraph (2)” and inserting “paragraph  
6 (2) or (3)”;

7 (2) by redesignating paragraphs (2) and (3) as  
8 paragraphs (3) and (4), respectively; and

9 (3) by inserting after paragraph (1) the follow-  
10 ing:

11 “(2)(A) Any person who submits a report under sec-  
12 tion 510(k) for a type of device that has not been pre-  
13 viously classified under this Act, and which is classified  
14 into class III under paragraph (1), may request, within  
15 30 days after receiving written notice of such a classifica-  
16 tion, the Secretary to classify the device into class I or  
17 II under the criteria set forth in subsection (a)(1). The  
18 person may, in the request, recommend to the Secretary  
19 the classification for the device. The request shall describe  
20 the device and provide detailed information and reasons  
21 for the recommended classification.

22 “(B)(i) Not later than 60 days after the date of the  
23 request under subparagraph (A) for classification of a de-  
24 vice under the criteria set forth in subparagraphs (A)  
25 through (C) of section 513(a)(1), the Secretary shall by  
26 written order classify the device. Such classification shall

1 be the initial classification of the device for purposes of  
 2 paragraph (1) and any device classified under this para-  
 3 graph into class I or II shall be a predicate device for de-  
 4 termining substantial equivalence under paragraph (1).

5 “(ii) A device that remains in class III under this  
 6 subparagraph shall be deemed adulterated within the  
 7 meaning of section 501(f)(1)(B) until approved under sec-  
 8 tion 515 or exempted from such approval under section  
 9 520(g).

10 “(C) Following the issuance of an order classifying  
 11 a device under this paragraph, the Secretary shall, within  
 12 30 days after the date of the issuance of the order, publish  
 13 a notice in the Federal Register announcing such classi-  
 14 fication.”.

15 **SEC. 606. SECRETARY'S DISCRETION TO TRACK DEVICES.**

16 (a) **RELEASE OF INFORMATION.**—Section 519(e) (21  
 17 U.S.C. 360i(e)) is amended by adding at the end the fol-  
 18 lowing flush sentence:

19 “Any patient receiving a device subject to tracking under  
 20 this section may refuse to release, or refuse permission  
 21 to release, the patient's name, address, social security  
 22 number, or other identifying information for the purpose  
 23 of tracking.”.

24 (b) **PUBLICATION OF CERTAIN DEVICES.**—Not later  
 25 than 180 days after the date of enactment of this Act,

1 the Secretary shall develop and publish in the Federal  
 2 Register a list that identifies each type of device subject  
 3 to tracking under section 519(e)(1) of the Federal Food,  
 4 Drug, and Cosmetic Act (21 U.S.C. 360i(e)). Each device  
 5 not identified by the Secretary under this subsection shall  
 6 be deemed to be exempt from the mandatory tracking re-  
 7 quirement under section 519 of such Act.

8 **SEC. 607. SECRETARY'S DISCRETION TO CONDUCT**  
 9 **POSTMARKET SURVEILLANCE.**

10 (a) IN GENERAL.—Section 522 (21 U.S.C. 360l) is  
 11 amended by striking “SEC. 522.” and all that follows  
 12 through “(2) DISCRETIONARY SURVEILLANCE.—The” and  
 13 inserting the following:

14 “SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—  
 15 The”.

16 (b) SURVEILLANCE APPROVAL.—Section 522(b) (21  
 17 U.S.C. 360l(b)) is amended to read as follows:

18 “(b) SURVEILLANCE APPROVAL.—

19 “(1) IN GENERAL.—Each manufacturer re-  
 20 quired to conduct a surveillance of a device under  
 21 subsection (a) shall, not later than 30 days after re-  
 22 ceiving notice from the Secretary that the manufac-  
 23 turer is required under this section to conduct the  
 24 surveillance, submit for the approval of the Sec-  
 25 retary, a plan for the required surveillance.

1           “(2) DETERMINATION.—Not later than 60 days  
 2           after the receipt of the plan, the Secretary shall de-  
 3           termine if a person proposed to be used to conduct  
 4           the surveillance has sufficient qualifications and ex-  
 5           perience to conduct the surveillance and if the plan  
 6           will result in the collection of useful data that can  
 7           reveal unforeseen adverse events or other informa-  
 8           tion necessary to protect the public health and to  
 9           provide safety and effectiveness information for the  
 10          device.

11           “(3) LIMITATION ON PLAN APPROVAL.—The  
 12          Secretary may not approve the plan until the plan  
 13          has been reviewed by a qualified scientific and tech-  
 14          nical review committee established by the Sec-  
 15          retary.”.

16          (c) DURATION OF SURVEILLANCE.—Section 522 (21  
 17          U.S.C. 360l), as amended by subsection (b), is further  
 18          amended by adding at the end the following:

19           “(c) DURATION OF SURVEILLANCE.—

20           “(1) IN GENERAL.—Each manufacturer re-  
 21          quired to conduct a surveillance of a device under  
 22          subsection (a) shall be required to conduct such sur-  
 23          veillance for not longer than 24 months.

24           “(2) EXTENSION OF THE PERIOD OF SURVEIL-  
 25          LANCE.—If the Secretary determines that additional

1 surveillance is needed to identify the incidence of ad-  
 2 verse events documented during the initial period of  
 3 surveillance that were not foreseen at the time of ap-  
 4 proval or classification of the device; the Secretary  
 5 may extend the period of surveillance for such time  
 6 as may be necessary after providing the person re-  
 7 quired to conduct such surveillance an opportunity  
 8 for an informal hearing to determine whether or not  
 9 additional surveillance is appropriate and to deter-  
 10 mine the appropriate period, if any, for such surveil-  
 11 lance.”.

12 **SEC. 608. REPORTING.**

13 Section 519 (21 U.S.C. 360i) is amended—

14 (1) by striking “, importer, or distributor” each  
 15 place it appears and inserting “or importer”;

16 (2) in subsection (a)—

17 (A) in paragraph (7), by striking the semi-  
 18 colon at the end and inserting “; and”;

19 (B) in paragraph (8), by striking “; and”  
 20 and inserting a period; and

21 (C) by striking paragraph (9); and

22 (3) by striking subsection (d).

23 **SEC. 609. PILOT AND SMALL-SCALE MANUFACTURE.**

24 Section 505(c) (21 U.S.C. 355(c)) is amended by  
 25 adding at the end the following:

1       “(4) An application shall be approved based on infor-  
2 mation obtained from products manufactured in a pilot  
3 or other small facility so long as the commercial manufac-  
4 turing process is validated prior to product distribution  
5 pursuant to a protocol submitted with the application, un-  
6 less the Secretary specifies in writing the reasons why in-  
7 formation from a full scale production facility is necessary  
8 to ensure the safety or effectiveness of the drug.”.

9   **SEC. 610. REQUIREMENTS FOR RADIOPHARMACEUTICALS.**

10       (a) REQUIREMENTS.—

11           (1) REGULATIONS.—Not later than 180 days  
12 after the date of enactment of this Act, the Sec-  
13 retary of Health and Human Services, after con-  
14 sultation with patient advocacy groups, associations,  
15 physicians licensed to use radiopharmaceuticals, and  
16 the regulated industry, shall establish proposed regu-  
17 lations governing the approval of  
18 radiopharmaceutical articles designed for diagnosis  
19 and monitoring of diseases and conditions. The reg-  
20 ulations shall provide that the safety and effective-  
21 ness of a radiopharmaceutical shall be evaluated tak-  
22 ing into account the appropriate use of  
23 radiopharmaceutical in the practice of medicine, the  
24 pharmacological and toxicological activity of the  
25 radiopharmaceutical, and the estimated absorbed ra-

1 diation dose of the radiopharmaceutical. Not later  
 2 than 1 year after the date of enactment of this Act,  
 3 the Secretary shall promulgate the final regulations  
 4 governing the approval of the radiopharmaceutical.

5 (2) SPECIAL RULE.—In the case of a  
 6 radiopharmaceutical intended to be used for diag-  
 7 nostic purposes, the indications for which such  
 8 radiopharmaceutical is approved for marketing may  
 9 refer to manifestations of disease (such as bio-  
 10 chemical, physiological, anatomic, or pathological  
 11 processes) common to or present in 1 or more dis-  
 12 ease states, or may refer to a diagnostic procedure  
 13 used in the diagnosis of 1 or more diseases or condi-  
 14 tions.

15 (b) DEFINITION.—In this section, the term  
 16 “radiopharmaceutical” means—

17 (1) an article—

18 (A) that is intended for use in vivo in the  
 19 diagnosis, cure, mitigation, treatment, or pre-  
 20 vention of a disease or a manifestation of dis-  
 21 ease in man; and

22 (B) that exerts its primary effect through  
 23 its pharmacokinetics and the spontaneous dis-  
 24 integration of unstable nuclei with the emission  
 25 of ionizing radiation; or

1           (2) a reagent kit or nuclide generator that is  
 2           intended to be used in the preparation of any such  
 3           article.

4   **SEC. 611. MODERNIZATION OF REGULATION OF BIOLOGI-**  
 5           **CAL PRODUCTS.**

6           (a) LICENSES.—

7           (1) IN GENERAL.—Section 351(a) of the Public  
 8           Health Service (42 U.S.C. 262(a)) is amended to  
 9           read as follows:

10           REGULATION OF BIOLOGICAL PRODUCTS

11           “SEC. 351. (a)(1) Except as provided in paragraph  
 12           (4), no person shall introduce or deliver for introduction  
 13           into interstate commerce any biological product unless—

14           “(A) a biologics license is in effect for the bio-  
 15           logical product; and

16           “(B) each package of the biological product is  
 17           plainly marked with the proper name of the biologi-  
 18           cal product contained in the package; the name; ad-  
 19           dress; and applicable license number of the manufac-  
 20           turer of the biological product; and the expiration  
 21           date of the biological product.

22           “(2)(A) The Secretary shall establish, by regulation,  
 23           requirements for the approval, suspension, and revocation  
 24           of biologics licenses.

25           “(B) A biologics license application shall be approved  
 26           based upon a demonstration that—



1           “(i) the biological product that is the subject of  
2           the application is safe, pure, and potent; and

3           “(ii) the facility in which the biological product  
4           is manufactured, processed, packed, or held meets  
5           standards designed to assure that the biological  
6           product continues to be safe, pure, and potent.

7           “(3) A demonstration under paragraph (2)(B)(i) may  
8           be made on the basis of 1 or more clinical trials, or other  
9           requirements established by the Secretary under section  
10          505 of the Federal Food, Drug, and Cosmetic Act (21  
11          U.S.C. 355).

12          “(4) The Secretary shall prescribe requirements  
13          under which a biological product undergoing investigation  
14          shall be exempt from the requirements of paragraph (1).”.

15                 (2) ~~ELIMINATION OF EXISTING LICENSE RE-~~  
16          ~~QUIREMENT.~~—Section 351(d) of the Public Health  
17          Service Act (42 U.S.C. 262(d)) is amended—

18                 (A) by striking “(d)(1)” and all that follows  
19          through “of this section.”;

20                 (B) in paragraph (2),

21                         (i) by striking “(2)(A) Upon” and insert-  
22                         ing “(d)(1) Upon”; and

23                         (ii) by redesignating subparagraph (B) as  
24                         paragraph (2); and

1           (C) in paragraph (2), (as so redesignated by  
2           subparagraph (B)(ii)), by striking “subparagraph  
3           (A)” and inserting “paragraph (1)”.

4           (b) LABELING.—Section 351(b) of the Public Health  
5           Service Act (42 U.S.C. 262(b)) is amended to read as fol-  
6           lows:

7           “(b) No person shall falsely label or mark any pack-  
8           age or container of any biological product or alter any  
9           label or mark on the package or container so as to falsify  
10          the label or mark.”.

11          (c) INSPECTION.—Section 351(c) of the Public  
12          Health Service Act (42 U.S.C. 262(c)) is amended by  
13          striking “virus, serum,” and all that follows and inserting  
14          “biological product.”.

15          (d) DEFINITION; APPLICATION.—Part F of title III  
16          of the Public Health Service Act (42 U.S.C. 262 et seq.)  
17          is amended by adding at the end the following:

18          “(i) For purposes of this section, the term “biological  
19          product” means a virus, therapeutic serum, toxin, anti-  
20          toxin, vaccine, blood, blood component or derivative, aller-  
21          genic product, analogous product, or arsphenamine or its  
22          derivatives (or any other trivalent organic arsenic  
23          compound) applicable to the prevention, treatment, or  
24          cure of diseases or conditions of human beings.”.

1 (e) CONFORMING AMENDMENT.—Section 503(g)(4)  
 2 (21 U.S.C. 353(g)(4)) is amended—

3 (1) in subparagraph (A), by striking “section  
 4 351(a)” and inserting “section 351(i)”; and

5 (2) in subparagraph (B)(iii), by striking “prod-  
 6 uct or establishment license under subsection (a) or  
 7 (d)” and inserting “biologics license application  
 8 under subsection (a)”.

9 (f) SPECIAL RULE.—The Secretary of Health and  
 10 Human Services shall take measures to minimize dif-  
 11 ferences in the review and approval of products required  
 12 to have biological license applications under section 351  
 13 of the Public Health Service Act (42 U.S.C. 262) and  
 14 products required to have full new drug applications under  
 15 section 505(b)(1) of the Federal Food, Drug, and Cos-  
 16 metic Act (21 U.S.C. 355).

17 **SEC. 612. SUPPLEMENTAL NEW DRUG APPLICATIONS.**

18 Section 505(d) (21 U.S.C. 355(d)) is amended by  
 19 adding at the end the following:

20 “(7) The Secretary may approve a supplement to an  
 21 approved application for an additional use for the drug  
 22 on the basis of literature reports, reliable clinical experi-  
 23 ence, or persuasive scientific evidence, the totality of which  
 24 is sufficient to demonstrate the effectiveness of the drug  
 25 for the use involved.”.

1 **SEC. 613. HEALTH CARE ECONOMIC INFORMATION.**

2 Section 502 (21 U.S.C. 352) is amended by adding  
3 at the end the following:

4 “(u) In the case of a health care economic statement  
5 that is included in labeling or advertising provided to a  
6 formulary committee, managed care organization, or simi-  
7 lar entity with responsibility for drug selection decisions  
8 (other than the label or approved physician package insert  
9 relating to an indication approved under section 505 or  
10 351 of the Public Health Service Act) if the health care  
11 economic statement is not competent and reliable. Any  
12 such statement shall be subject solely to this paragraph.  
13 In this paragraph, the term ‘health care economic state-  
14 ment’ means any statement that identifies, measures, or  
15 compares the costs (direct, indirect, and intangible) and  
16 health care consequences of a drug to another drug or to  
17 another health care intervention for the same indication,  
18 or to no intervention, where the primary endpoint is an  
19 economic outcome.”.

20 **SEC. 614. EXPEDITING STUDY AND APPROVAL OF FAST**  
21 **TRACK DRUGS.**

22 (a) IN GENERAL.—Chapter V (21 U.S.C. 351 et  
23 seq.), as amended by section 102, is further amended by  
24 adding at the end the following:

1           “SUBCHAPTER E—FAST TRACK DRUGS

2   **“SEC. 561. FAST TRACK DRUGS.**

3       “(a) DESIGNATION OF DRUG AS A FAST TRACK  
4 DRUG.—

5           “(1) IN GENERAL.—The Secretary shall facili-  
6 tate development, and expedite approval, of new  
7 drugs and biological products that are intended for  
8 the treatment of serious or life-threatening condi-  
9 tions and that demonstrate the potential to address  
10 unmet medical needs for such conditions. For pur-  
11 poses of this Act, such products shall be known as  
12 ‘fast track drugs’.

13           “(2) REQUEST FOR DESIGNATION.—The spon-  
14 sor of a drug may request the Secretary to designate  
15 the drug as a fast track drug. A request for designa-  
16 tion may be made concurrently with, or at any time  
17 after, submission of an application for the investiga-  
18 tion of the drug under section 505(i).

19           “(3) DESIGNATION.—Within 30 calendar days  
20 after the receipt of a request under paragraph (2),  
21 the Secretary shall determine whether the drug that  
22 is the subject of the request is being, or will be, in-  
23 vestigated for treatment of a condition described in  
24 paragraph (1). If the Secretary finds that the drug  
25 is intended for such treatment, the Secretary shall

1 designate the drug as a fast track drug and shall  
 2 take such actions as are appropriate to expedite the  
 3 development and review of the drug.

4 ~~“(b) APPROVAL OF APPLICATION FOR A FAST TRACK~~  
 5 ~~DRUG.—~~

6 ~~“(1) IN GENERAL.—~~The Secretary may approve  
 7 an application for approval of a fast track drug  
 8 under section 505(b) or section 351 of the Public  
 9 Health Service Act upon a determination that the  
 10 drug has an effect on a surrogate endpoint that is  
 11 reasonably likely to predict clinical benefit.

12 ~~“(2) LIMITATION.—~~Approval under this sub-  
 13 section may be subject to the requirement that the  
 14 sponsor conduct appropriate post-approval studies to  
 15 validate the surrogate endpoint or otherwise confirm  
 16 the clinical benefit of the drug.

17 ~~“(c) REVIEW OF INCOMPLETE APPLICATIONS FOR~~  
 18 ~~APPROVAL OF A FAST TRACK DRUG.—~~

19 ~~“(1) IN GENERAL.—~~The Secretary shall, after  
 20 completion of the pivotal clinical trial for a fast  
 21 track drug under investigation, accept for filing and  
 22 commence review of an incomplete application for  
 23 the drug’s approval if the application includes a  
 24 schedule for submission of information necessary to

1 make the application complete and any fee that may  
2 be required under section 736.

3 ~~“(2) EXCEPTION.—Any time period for review~~  
4 ~~of human drug applications agreed to by the Sec-~~  
5 ~~retary under section 736 shall not apply to applica-~~  
6 ~~tions submitted under paragraph (1) until a com-~~  
7 ~~pleted application is submitted.~~

8 ~~“(d) AWARENESS EFFORTS.—The Secretary shall—~~

9 ~~“(1) develop and widely disseminate to physi-~~  
10 ~~cians; patient organizations; pharmaceutical and bio-~~  
11 ~~technology companies and other appropriate persons~~  
12 ~~a comprehensive description of the provisions appli-~~  
13 ~~cable to fast track drugs established under this sec-~~  
14 ~~tion; and~~

15 ~~“(2) establish an ongoing program to encourage~~  
16 ~~the development and use of surrogate endpoints that~~  
17 ~~are reasonably likely to predict clinical benefit for all~~  
18 ~~serious and life-threatening conditions for which~~  
19 ~~there exist significant unmet medical needs.”.~~

20 ~~(b) REGULATIONS.—Within 90 days after the date of~~  
21 ~~enactment of this Act, the Secretary shall issue guidelines~~  
22 ~~for fast track drugs that implement the requirements of~~  
23 ~~section 561 of the Federal Food, Drug, and Cosmetic Act.~~

1 **SEC. 615. MANUFACTURING CHANGES FOR DRUGS AND BIO-**  
 2 **LOGICS.**

3 Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 4 section 602, is further amended by adding at the end the  
 5 following:

6 “SUBCHAPTER E—MANUFACTURING CHANGES

7 “SEC. 751. MANUFACTURING CHANGES.

8 “(a) IN GENERAL.—A change in the manufacture of  
 9 a new drug, including a biological product, may be made  
 10 in accordance with this section:

11 “(b) CHANGES.—

12 “(1) VALIDATION.—Before distributing a drug  
 13 made after a change in the manufacture of the drug  
 14 from the manufacturing process established in the  
 15 approved new drug application under section 505, or  
 16 license application under section 351 of the Public  
 17 Health Service Act, the applicant shall validate the  
 18 effect of the change on the identity, strength, qual-  
 19 ity, purity, and potency as the identity, strength,  
 20 quality, purity, and potency may relate to the safety  
 21 or effectiveness of the drug:

22 “(2) REPORTS.—The applicant shall report a  
 23 change described in paragraph (1) to the Secretary  
 24 and may distribute a drug made after the change as  
 25 follows:



1           “(A)(i) Major manufacturing changes,  
2           which are of a type determined by the Secretary  
3           to have a substantial potential to adversely af-  
4           fect the identity, strength, quality, purity, and  
5           potency as the identity, strength, quality, pu-  
6           rity, and potency may relate to the safety or ef-  
7           fectiveness of a drug, shall be submitted to the  
8           Secretary in a supplemental application and  
9           drugs made after such changes may not be dis-  
10          tributed until the Secretary approves the sup-  
11          plemental application.

12           “(ii) In this subparagraph, the term ‘major  
13          manufacturing changes’ means—

14                   “(I) changes in the qualitative or  
15                   quantitative formulation or the specifica-  
16                   tions in the approved marketing applica-  
17                   tion (unless exempted by the Secretary);

18                   “(II) changes which the Secretary de-  
19                   termines by regulation or guidance require  
20                   completion of an appropriate human study  
21                   demonstrating equivalence to the drug  
22                   manufactured before such changes; and

23                   “(III) other changes which the Sec-  
24                   retary determines by regulation or guid-  
25                   ance have a substantial potential to ad-

1                   versely affect the safety or effectiveness of  
2                   the drug.

3                   “(B)(i) As determined by the Secretary,  
4                   manufacturing changes other than major manu-  
5                   facturing changes shall—

6                   “(I) be made at any time and re-  
7                   ported annually to the Secretary, with sup-  
8                   porting data; or

9                   “(II) be reported to the Secretary in  
10                  a supplemental application.

11                  “(ii) In the case of changes made in ac-  
12                  cordance with clause (i)(II);

13                  “(I) the applicant may distribute the  
14                  drug 30 days after the supplemental appli-  
15                  cation is received by the Secretary unless  
16                  the Secretary notifies the applicant within  
17                  such 30-day period that prior approval of  
18                  such supplemental application is required;  
19                  and

20                  “(II) the Secretary shall, after the no-  
21                  tification to an applicant under subclause  
22                  (I), approve or disapprove each such sup-  
23                  plemental application.

24                  “(ii) The Secretary may determine types of  
25                  manufacturing changes after which distribution

1           of a drug may commence at the time of submis-  
 2           sion of such supplemental application.”.

3       (b) ~~EXISTING LAW.~~—The requirements of the Fed-  
 4       eral Food, Drug, and Cosmetic Act and the Public Health  
 5       Service Act in effect on the date of enactment of this Act  
 6       with respect to manufacturing changes shall remain in ef-  
 7       fect for—

8           (1) a period of 24 months after the date of the  
 9       enactment of this Act; or

10          (2) until the effective date of regulations pro-  
 11       mulgated by the Secretary implementing section 751  
 12       of the Federal Food, Drug, and Cosmetic Act,  
 13       whichever is sooner.

14       **SEC. 616. DATA REQUIREMENTS FOR DRUGS AND BIO-**  
 15                               **LOGICS.**

16       Within 12 months after the date of enactment of this  
 17       Act, the Secretary, through the Commissioner of Food and  
 18       Drugs, shall issue guidance that describes when abbre-  
 19       viated study reports in lieu of full reports may be submit-  
 20       ted with a new drug application for certain types of stud-  
 21       ies. Such guidance will describe the kinds of studies for  
 22       which abbreviated reports are appropriate and the appro-  
 23       priate abbreviated report formats.

1 **SEC. 617. FOOD CONTACT SUBSTANCES.**

2 (a) **FOOD CONTACT SUBSTANCES.**—Section 409(a)  
3 (~~21 U.S.C. 348(a)~~) is amended—

4 (1) in paragraph (1), by striking at the end  
5 “or”;

6 (2) by striking the period at the end of para-  
7 graph (2) and inserting “; or”;

8 (3) by inserting after paragraph (2) the follow-  
9 ing:

10 “(3) in the case of a food additive as defined  
11 in this Act that is a food contact substance, there  
12 is—

13 “(A) in effect, and such substance and the  
14 use of such substance are in conformity with, a  
15 regulation issued under this section prescribing  
16 the conditions under which such additive may  
17 be safely used; or

18 “(B) a notification submitted under sub-  
19 section (h) which is effective.”; and

20 (4) by striking the matter following paragraph  
21 (3) (as added by paragraph (2)) and inserting the  
22 following flush sentence:

23 “While such a regulation relating to a food additive, or  
24 such a notification under subsection (h) relating to a food  
25 additive that is a food contact substance ; is in effect, and  
26 has not been revoked pursuant to subsection (j), a food

1 shall not, by reason of bearing or containing such a food  
 2 additive in accordance with the regulation or notification,  
 3 be considered adulterated under section 402(a)(1).”.

4 (b) NOTIFICATION FOR FOOD CONTACT SUB-  
 5 STANCES.—Section 409 (21 U.S.C. 348), as amended by  
 6 subsection (a), is further amended—

7 (1) by redesignating subsections (h) and (i), as  
 8 subsections (i) and (j), respectively;

9 (2) by inserting after subsection (g) the follow-  
 10 ing:

11 “NOTIFICATION RELATING TO A FOOD CONTACT  
 12 SUBSTANCE

13 “(h)(1) Subject to such regulations as may be pro-  
 14 mulgated under paragraph (3), a manufacturer or supplier  
 15 of a food contact substance may, at least 120 days prior  
 16 to the introduction or delivery for introduction into inter-  
 17 state commerce of the food contact substance, notify the  
 18 Secretary of the identity and intended use of the food con-  
 19 tact substance, and of the determination of the manufac-  
 20 turer or supplier that the intended use of such food con-  
 21 tact substance is safe under the standard described in sub-  
 22 section (c)(3)(A). The notification shall contain the infor-  
 23 mation that forms the basis of the determination, the fee  
 24 required under paragraph (5), and all information re-

1 quired to be submitted by regulations promulgated by the  
2 Secretary.

3       ~~“(2)(A) A notification submitted under paragraph (1)~~  
4 ~~shall become effective 120 days after the date of receipt~~  
5 ~~by the Secretary and the food contact substance may be~~  
6 ~~introduced or delivered for introduction into interstate~~  
7 ~~commerce, unless the Secretary makes a determination~~  
8 ~~within the 120-day period that, based on the data and in-~~  
9 ~~formation before the Secretary, such use of the food con-~~  
10 ~~tact substance has not been shown to be safe under the~~  
11 ~~standard described in subsection (c)(3)(A), and informs~~  
12 ~~the manufacturer or supplier of such determination.~~

13       ~~“(B) A decision by the Secretary to object to a notifi-~~  
14 ~~cation shall constitute final agency action subject to judi-~~  
15 ~~cial review.~~

16       ~~“(C) For purposes of this paragraph, ‘food contact~~  
17 ~~substance’ means the substance that is the subject of a~~  
18 ~~notification submitted under paragraph (1), and does not~~  
19 ~~include a similar or identical substance manufactured or~~  
20 ~~prepared by a person other than the manufacturer identi-~~  
21 ~~fied in the notification.~~

22       ~~“(3)(A) The process in this subsection shall be uti-~~  
23 ~~lized for authorizing the marketing of a food contact sub-~~  
24 ~~stance except where the Secretary determines that submis-~~  
25 ~~sion and review of a petition under subsection (b) is nec-~~

1    essary to provide adequate assurance of safety, or where  
2    the Secretary and any manufacturer or supplier agree that  
3    such manufacturer or supplier may submit a petition  
4    under subsection (b).

5       “(B) The Secretary is authorized to promulgate regu-  
6    lations to identify the circumstances in which a petition  
7    shall be filed under subsection (b), and shall consider cri-  
8    teria such as the probable consumption of such food con-  
9    tact substance and potential toxicity of the food contact  
10   substance in determining the circumstances in which a pe-  
11   tition shall be filed under subsection (b).

12       “(4) The Secretary shall keep confidential any infor-  
13   mation provided in a notification under paragraph (1) for  
14   120 days after receipt by the Secretary of the notification.  
15   After the expiration of such 120 days, the information  
16   shall be available to any interested party except for mat-  
17   ters in the notification that is a trade secret or confidential  
18   commercial information.

19       “(5)(A) Each person that submits a notification re-  
20   garding a food contact substance under this section shall  
21   be subject to the payment of a reasonable fee. The fee  
22   shall be based on the resources required to process the  
23   notification including reasonable administrative costs for  
24   such processing.

1       “(B) The Secretary shall conduct a study of the costs  
 2 of administering the notification program established  
 3 under this section and, on the basis of the results of such  
 4 study, shall, within 18 months after the date of enactment  
 5 of this subsection, promulgate regulations establishing the  
 6 fee required by subparagraph (A).  
 7

8       “(C) A notification submitted without the appropriate  
 9 fee is not complete and shall not become effective for the  
 10 purposes of paragraph (3) until the appropriate fee is  
 11 paid.  
 12

13       “(D) Fees collected pursuant to this subsection—  
 14

15               “(i) shall not be deposited as an offsetting col-  
 16 lection to the appropriations for the Department of  
 17 Health and Human Services;  
 18

19               “(ii) shall be credited to the appropriate ac-  
 20 count of the Food and Drug Administration; and  
 21

22               “(iii) shall be available in accordance with ap-  
 23 propriation Acts until expended, without fiscal year  
 24 limitation.  
 25

26       “(6) In this section, the term ‘food contact substance’  
 27 means any substance intended for use as a component of  
 28 materials used in manufacturing, packing, packaging,  
 29 transporting, or holding food if such use is not intended  
 30 to have any technical effect in such food.”;  
 31



1           ~~(3)~~ in subsection ~~(i)~~, as so redesignated by  
 2           paragraph ~~(1)~~, by adding at the end the following:  
 3           ~~“The Secretary shall by regulation prescribe the pro-~~  
 4           ~~cedure by which the Secretary may deem a notifica-~~  
 5           ~~tion under subsection (h) to no longer be effective.~~

6           ~~(4)~~ in subsection ~~(j)~~, as so redesignated by  
 7           paragraph ~~(1)~~, by striking “subsections ~~(b) to (h)~~”  
 8           and inserting “subsections ~~(b) to (i)~~”.

9           ~~(c) EFFECTIVE DATE.—~~Notifications under section  
 10       ~~409(h)~~ of the Federal Food, Drug, and Cosmetic Act, as  
 11       added by subsection ~~(b)~~, may be submitted beginning 18  
 12       months after the date of the enactment of this Act.

13       **SEC. 618. HEALTH CLAIMS OF FOOD PRODUCTS.**

14           Section ~~403(r)(3)~~ (21 U.S.C. ~~343(r)(3)~~) is amended  
 15       by adding at the end the following:

16           ~~“(C)~~ Notwithstanding the provisions of clauses ~~(A)(i)~~  
 17       and ~~(B)~~, a claim of the type described in subparagraph  
 18       ~~(1)(B)~~ which is not authorized by the Secretary in a regu-  
 19       lation promulgated in accordance with clause shall be au-  
 20       thorized and may be made if—

21           ~~“(i)~~ an authoritative scientific body of the  
 22       United States Government with official responsibility  
 23       for public health protection or research directly re-  
 24       lating to human nutrition (such as the National In-  
 25       stitutes of Health or the Centers for Disease Control

1 and Prevention); the National Academy of Sciences;  
 2 or subdivisions of the scientific body or the National  
 3 Academy of Sciences, has published statements, con-  
 4 clusions, or recommendations in effect recognizing  
 5 that the relationship between the nutrient and dis-  
 6 ease or health-related condition to which the claim  
 7 refers is supported by pertinent scientific evidence;  
 8 and

9 “(ii) the manufacturer or distributor of the food  
 10 for which such claim is made has submitted to the  
 11 Secretary at least 90 days before the first introduc-  
 12 tion of such food into interstate commerce a notice  
 13 of claim, including a concise description of the basis  
 14 upon which such manufacturer or distributor relied  
 15 for determining that the requirements of clause (i)  
 16 have been satisfied.”.

17 **SEC. 619. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.**

18 Chapter V of the Federal Food, Drug, and Cosmetic  
 19 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
 20 section 505 the following:

21 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

22 “(a) **MARKET EXCLUSIVITY FOR NEW DRUGS.**—If,  
 23 prior to approval of an application that is submitted under  
 24 section 505(b)(1) the Secretary determines that informa-  
 25 tion relating to the use of a drug in the pediatric popu-

1 lation may produce health benefits in that population; the  
 2 Secretary makes a written request for pediatric studies  
 3 (which may include a time frame for completing such stud-  
 4 ies); and such studies are completed within any such time  
 5 frame and the reports thereof submitted in accordance  
 6 with subsection (d)(2) or completed within any such time  
 7 frame and the reports thereof are accepted in accordance  
 8 with subsection (d)(3)—

9           “(1)(A) the period during which an application  
 10 may not be submitted under subsections  
 11 (e)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be  
 12 five years and six months rather than five years; and  
 13 the references in subsections (e)(3)(D)(ii) and  
 14 (j)(4)(D)(ii) of section 505 to four years; to forty-  
 15 eight months; and to seven and one-half years shall  
 16 be deemed to be four and one-half years; fifty-four  
 17 months; and eight years; respectively; or

18           “(B) the period of market exclusivity under  
 19 subsections (e)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)  
 20 and (iv) of section 505 shall be three years and six  
 21 months rather than three years; and

22           “(2)(A) if the drug is the subject of—

23           “(i) a listed patent for which a certification  
 24 has been submitted under section  
 25 505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and

1           for which pediatric studies were submitted prior  
 2           to the expiration of the patent (including any  
 3           patent extensions); or

4           “(ii) a listed patent for which a certifi-  
 5           cation has been submitted under section  
 6           505(b)(2)(A)(iii)                   or           section  
 7           505(j)(2)(A)(vii)(III),

8           the period during which an application may not be  
 9           approved under section 505(e)(3) or section  
 10          505(j)(4)(B) shall be extended by a period of six  
 11          months after the date the patent expires (including  
 12          any patent extensions); or

13          “(B) if the drug is the subject of a listed patent  
 14          for which a certification has been submitted under  
 15          section 505(b)(2)(A)(iv)           or           section  
 16          505(j)(2)(A)(vii)(IV), and in the patent infringement  
 17          litigation resulting from the certification the court  
 18          determines that the patent is valid and would be in-  
 19          fringed, the period during which an application may  
 20          not be approved under section 505(e)(3) or section  
 21          505(j)(4)(B) shall be extended by a period of six  
 22          months after the date the patent expires (including  
 23          any patent extensions).

24          “(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR  
 25          WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE

1 BENEFICIAL.—Not later than 180 days after the date of  
 2 enactment of this section, the Secretary, after consultation  
 3 with experts in pediatric research (such as the American  
 4 Academy of Pediatrics, the Pediatric Pharmacology Re-  
 5 search Unit Network, and the United States Pharma-  
 6 copoeia) shall develop and publish an initial list of ap-  
 7 proved drugs for which additional pediatric information  
 8 may produce health benefits in the pediatric population.  
 9 The Secretary shall annually update the list.

10 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-  
 11 KETED DRUGS.—If the Secretary makes a written request  
 12 for pediatric studies (which may include a time frame for  
 13 completing such studies) concerning a drug identified in  
 14 the list described in subsection (b) to the holder of an ap-  
 15 proved application under section 505(b)(1) for the drug,  
 16 the holder agrees to the request, and the studies are com-  
 17 pleted within any such time frame and the reports thereof  
 18 submitted in accordance with subsection (d)(2) or com-  
 19 pleted within any such time frame and the reports thereof  
 20 accepted in accordance with subsection (d)(3)—

21 “(1)(A) the period during which an application  
 22 may not be submitted under subsections  
 23 (e)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be  
 24 five years and six months rather than five years, and  
 25 the references in subsections (e)(3)(D)(ii) and

1       ~~(j)(4)(D)(ii)~~ of section 505 to four years, to forty-  
 2       eight months, and to seven and one-half years shall  
 3       be deemed to be four and one-half years, ~~fifty-four~~  
 4       months, and eight years, respectively; or

5       “~~(B)~~ the period of market exclusivity under  
 6       subsections ~~(c)(3)(D)~~ (iii) and (iv) and ~~(j)(4)(D)~~ (iii)  
 7       and (iv) of section 505 shall be three years and six  
 8       months rather than three years; and

9       “~~(2)(A)~~ if the drug is the subject of—

10       “~~(i)~~ a listed patent for which a certification  
 11       has been submitted under section  
 12       505(b)(2)(A)(ii) or ~~(j)(2)(A)(vii)(II)~~ and for  
 13       which pediatric studies were submitted prior to  
 14       the expiration of the patent (including any pat-  
 15       ent extensions); or

16       “~~(ii)~~ a listed patent for which a certifi-  
 17       cation has been submitted under section  
 18       505(b)(2)(A)(iii)                   or                   section  
 19       505(j)(2)(A)(vii)(III);

20       the period during which an application may not be  
 21       approved under section 505(c)(3) or section  
 22       505(j)(4)(B) shall be extended by a period of six  
 23       months after the date the patent expires (including  
 24       any patent extensions); or

1           “(B) if the drug is the subject of a listed patent  
 2           for which a certification has been submitted under  
 3           section       505(b)(2)(A)(iv)       or       section  
 4           505(j)(2)(A)(vii)(IV), and in the patent infringement  
 5           litigation resulting from the certification the court  
 6           determines that the patent is valid and would be in-  
 7           fringed, the period during which an application may  
 8           not be approved under section 505(e)(3) or section  
 9           505(j)(4)(B) shall be extended by a period of six  
 10          months after the date the patent expires (including  
 11          any patent extensions).

12       “(d) CONDUCT OF PEDIATRIC STUDIES.—

13           “(1) AGREEMENT FOR STUDIES.—The Sec-  
 14          retary may, pursuant to a written request for stud-  
 15          ies, after consultation with—

16                   “(A) the sponsor of an application for an  
 17                   investigational new drug under section 505(i),

18                   “(B) the sponsor of an application for a  
 19                   drug under section 505(b)(1), or

20                   “(C) the holder of an approved application  
 21                   for a drug under section 505(b)(1),  
 22          agree with the sponsor or holder for the conduct of  
 23          pediatric studies for such drug.

24           “(2) WRITTEN PROTOCOLS TO MEET THE  
 25          STUDIES REQUIREMENT.—If the sponsor or holder

1 and the Secretary agree upon written protocols for  
2 the studies; the studies requirement of subsection  
3 (a) or (c) is satisfied upon the completion of the  
4 studies and submission of the reports thereof in ac-  
5 cordance with the original written request and the  
6 written agreement referred to in paragraph (1). Not  
7 later than 60 days after the submission of the report  
8 of the studies, the Secretary shall determine if such  
9 studies were or were not conducted in accordance  
10 with the original written request and the written  
11 agreement and reported in accordance with the re-  
12 quirements of the Secretary for filing and so notify  
13 the sponsor or holder.

14 “(3) OTHER METHODS TO MEET THE STUDIES  
15 REQUIREMENT.—If the sponsor or holder and the  
16 Secretary have not agreed in writing on the proto-  
17 cols for the studies, the studies requirement of sub-  
18 section (a) or (c) is satisfied when such studies have  
19 been completed and the reports accepted by the Sec-  
20 retary. Not later than 90 days after the submission  
21 of the reports of the studies, the Secretary shall ac-  
22 cept or reject such reports and so notify the sponsor  
23 or holder. The Secretary’s only responsibility in ac-  
24 cepting or rejecting the reports shall be to deter-  
25 mine, within the 90 days, whether the studies fairly



1       respond to the written request, whether such studies  
 2       have been conducted in accordance with commonly  
 3       accepted scientific principles and protocols, and  
 4       whether such studies have been reported in accord-  
 5       ance with the requirements of the Secretary for fil-  
 6       ing.

7       “(e) ~~DELAY OF EFFECTIVE DATE FOR CERTAIN AP-~~  
 8       ~~PLICATIONS; PERIOD OF MARKET EXCLUSIVITY.~~—If the  
 9       Secretary determines that the acceptance or approval of  
 10      an application under section 505(b)(2) or 505(j) for a  
 11      drug may occur after submission of reports of pediatric  
 12      studies under this section, which were submitted prior to  
 13      the expiration of the patent (including any patent exten-  
 14      sion) or market exclusivity protection, but before the Sec-  
 15      retary has determined whether the requirements of sub-  
 16      section (d) have been satisfied, the Secretary shall delay  
 17      the acceptance or approval under section 505(b)(2) or  
 18      505(j), respectively, until the determination under sub-  
 19      section (d) is made, but such delay shall not exceed 90  
 20      days. In the event that requirements of this section are  
 21      satisfied, the applicable period of market exclusivity re-  
 22      ferred to in subsection (a) or (c) shall be deemed to have  
 23      been running during the period of delay.

24      “(f) ~~NOTICE OF DETERMINATIONS ON STUDIES RE-~~  
 25      ~~QUIREMENT.~~—The Secretary shall publish a notice of any

1 determination that the requirements of subsection (d)  
2 have been met and that submissions and approvals under  
3 section 505(b)(2) or (j) for a drug will be subject to the  
4 provisions of this section.

5 “(g) DEFINITIONS.—As used in this section, the term  
6 ‘pediatric studies’ or ‘studies’ means at least one clinical  
7 investigation (that, at the Secretary’s discretion, may in-  
8 clude pharmacokinetic studies) in pediatric age-groups in  
9 which a drug is anticipated to be used.

10 “(h) LIMITATION.—The holder of an approved appli-  
11 cation for a new drug that has already received six months  
12 of market exclusivity under subsection (a) or subsection  
13 (c) may, if otherwise eligible, obtain six months of market  
14 exclusivity under subsection (c)(1)(B) for a supplemental  
15 application, except that the holder is not eligible for exclu-  
16 sivity under subsection (c)(2).”

17 “(i) SUNSET.—No period of market exclusivity shall  
18 be granted under this section based on studies commenced  
19 after January 1, 2004. The Secretary shall conduct  
20 a study and report to Congress not later than January  
21 1, 2003 based on the experience under the program. The  
22 study and report shall examine all relevant issues, includ-  
23 ing—

1           “(1) the effectiveness of the program in improv-  
2           ing information about important pediatric uses for  
3           approved drugs;

4           “(2) the adequacy of the incentive provided  
5           under this section;

6           “(3) the economic impact of the program; and

7           “(4) any suggestions for modification that the  
8           Secretary deems appropriate.”.

## 9       **TITLE VII—FEES RELATING TO** 10       **DRUGS**

### 11   **SEC. 701. SHORT TITLE.**

12       This title may be cited as the “Prescription Drug  
13   Users Fee Reauthorization Act of 1997”.

### 14   **SEC. 702. FINDINGS.**

15       Congress finds that—

16           (1) prompt approval of safe and effective new  
17       drugs is critical to the improvement of the public  
18       health so that patients may enjoy the benefits pro-  
19       vided by the drugs to treat and prevent illness and  
20       disease;

21           (2) the public health will be served by making  
22       additional funds available for the purpose of aug-  
23       menting the resources of the Food and Drug Admin-  
24       istration that are devoted to the review of human  
25       drug applications;

1           ~~(3)~~ the provisions added by the Prescription  
 2     Drug User Fee Act of 1992, has been successful in  
 3     substantially reducing review times for human drug  
 4     applications and should be—

5                     (A) reauthorized for an additional 5 years;  
 6                     with certain technical improvements; and

7                     (B) carried out by the Food and Drug Ad-  
 8                     ministration with new commitments to imple-  
 9                     ment more ambitious and comprehensive im-  
 10                    provements in regulatory processes of the Food  
 11                    and Drug Administration; and

12           ~~(4)~~ the fees authorized by amendments made in  
 13     this title will be dedicated toward expediting the  
 14     drug development process and the review of human  
 15     drug applications as set forth in the goals identified  
 16     in the letters of \_\_\_\_\_; and  
 17     \_\_\_\_\_; from the Secretary of Health and  
 18     Human Services to the Chairman of the Committee  
 19     on Commerce of the House of Representatives and  
 20     the Chairman of Committee on Labor and Human  
 21     Resources Committee of the Senate, as set forth at  
 22     \_\_\_\_ Cong. Rec. \_\_\_\_\_ (daily ed. \_\_\_\_\_;  
 23     1997).

24 **SEC. 703. DEFINITIONS.**

25     Section 735 (21 U.S.C. 379g) is amended—

1           (1) in paragraph (1)—

2                   (A) by striking “Service Act, and” and in-  
3                   serting “Service Act,”; and

4                   (B) by striking “September 1, 1992.” and  
5                   inserting the following: “September 1, 1992,  
6                   does not include an application for a biological  
7                   product that is licensed for further manufactur-  
8                   ing use only, and does not include an applica-  
9                   tion or supplement submitted by a State or  
10                  Federal Government entity for a drug or bio-  
11                  logical product that is not distributed commer-  
12                  cially. Such term does include an application for  
13                  a large volume biological product intended for  
14                  single dose injection for intravenous use or in-  
15                  fusion.”;

16           (2) in paragraph (3)—

17                   (A) by striking “Service Act, and” and in-  
18                   serting “Service Act,”; and

19                   (B) by striking “September 1, 1992.” and  
20                   inserting the following: “September 1, 1992,  
21                   does not include a biological product that is li-  
22                   censed for further manufacturing use only, and  
23                   does not include a biological product that is not  
24                   distributed commercially and is the subject of a  
25                   supplement or application submitted by a State

1           or Federal Government entity. Such term does  
 2           include a large volume biological product in-  
 3           tended for single dose injection for intravenous  
 4           use or infusion.”;

5           (3) in paragraph (4), by striking “without” and  
 6           inserting “without substantial”;

7           (4) in paragraph (7)(A), by striking “employees  
 8           under contract” and all that follows through “Ad-  
 9           ministration,” and inserting “contractors of the  
 10          Food and Drug Administration,”;

11          (5) in paragraph (8)—

12                (A) in subparagraph (A)—

13                   (i) by striking “August of” and insert-  
 14                   ing “April of”; and

15                   (ii) by striking “August 1992” and in-  
 16                   serting “April 1992”; and

17                (B) by striking subparagraph (B) and in-  
 18                serting the following:

19                   “(B) the total percentage increase for such  
 20                   fiscal year since fiscal year 1997 in basic pay  
 21                   under the General Schedule in accordance with  
 22                   section 5332 of title 5, United States Code, as  
 23                   adjusted by any locality-based comparability  
 24                   payment pursuant to section 5304 of such title

1 for Federal employees stationed in the District  
2 of Columbia.”; and

3 ~~(6)~~ by adding at the end the following:

4 “~~(9)~~ The term ‘affiliate’ means, directly or indi-  
5 rectly,—

6 “(A) ~~1~~ business entity controls, or has the  
7 power to control, the other business entity; or

8 “(B) a third party controls, or has power  
9 to control both of the business entities de-  
10 scribed in subparagraph (A).”.

11 **SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.**

12 ~~(a)~~ TYPES OF FEES.—Section 736(a) ~~(21 U.S.C.~~  
13 ~~379h(a))~~ is amended—

14 ~~(1)~~ in paragraph (1)—

15 ~~(A)~~ by striking subparagraph (B) and in-  
16 serting the following:

17 “~~(B)~~ PAYMENT.—The fee required by sub-  
18 paragraph (A) shall be due upon submission of  
19 the application or supplement.”;

20 ~~(B)~~ in subparagraph (D)—

21 ~~(i)~~ in the subparagraph heading, by  
22 striking “NOT ACCEPTED” and inserting  
23 “REFUSED”;

24 ~~(ii)~~ by striking “50 percent” and in-  
25 serting “75 percent”;

1                   (iii) by striking “subparagraph  
2                   (B)(i)” and inserting “subparagraph (B);  
3                   and

4                   (iv) by striking “not accepted” and in-  
5                   serting “refused”; and

6                   (C) by adding at the end the following:

7                   “~~(E) EXCEPTION FOR DESIGNATED OR-~~  
8                   ~~PHAN DRUG OR INDICATION.—~~A human drug  
9                   application for a prescription drug product that  
10                  has been designated as a drug for a rare dis-  
11                  ease or condition pursuant to section 526, or a  
12                  supplement proposing to include a new indica-  
13                  tion for a rare disease or condition pursuant to  
14                  section 526, shall not be assessed a fee under  
15                  subparagraph (A), unless the human drug ap-  
16                  plication includes indications for other than  
17                  rare diseases or conditions:

18                  “~~(F) EXCEPTION FOR APPLICATIONS AND~~  
19                  ~~SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—~~  
20                  A human drug application or supplement that  
21                  includes an indication for use in pediatric popu-  
22                  lations shall be assessed a fee under subpara-  
23                  graph (A) only if—

24                   “(i) the application is for initial ap-  
25                   proval for use in a pediatric population; or



1                   “(ii) the application or supplement is  
 2                   for approval for use in pediatric and non-  
 3                   pediatric populations.

4                   “(G) REFUND OF FEE IF APPLICATION  
 5                   WITHDRAWN.—If an application or supplement  
 6                   is withdrawn after the application or supple-  
 7                   ment is filed, the Secretary may waive and re-  
 8                   fund the fee or a portion of the fee if no sub-  
 9                   stantial work was performed on the application  
 10                  or supplement after the application or supple-  
 11                  ment was filed. The Secretary shall have the  
 12                  sole discretion to waive and refund a fee or a  
 13                  portion of the fee under this subparagraph. A  
 14                  determination by the Secretary concerning a  
 15                  waiver or refund under this paragraph shall not  
 16                  be reviewable.”;

17                  (2) in paragraph (2)(A), by striking “505(j),  
 18                  and” and inserting the following: “505(j) or under  
 19                  an abbreviated new drug application pursuant to  
 20                  regulations in effect prior to the implementation of  
 21                  the Drug Price Competition and Patent Term Res-  
 22                  toration Act of 1984; or a product approved under  
 23                  an application under section 507 that is abbreviated;  
 24                  and”; and

25                  (3) in paragraph (3)—

1           (A) in subparagraph (A)—

2                 (i) in clause (i), by striking “is listed”  
3                 and inserting “has been submitted for list-  
4                 ing”; and

5                 (ii) by striking “Such fee shall be pay-  
6                 able” and all that follows through “section  
7                 510.” and inserting the following: “Such  
8                 fee shall be payable for the fiscal year in  
9                 which the product is first submitted for  
10                listing under section 510 or for relisting if  
11                the product has been withdrawn from list-  
12                ing or relisted and after such fee is paid  
13                for that fiscal year, such fee shall be pay-  
14                able on or before January 31 of each year.  
15                Such fee shall be paid only once for each  
16                product for the fiscal year in which a fee  
17                is payable.”; and

18           (B) in subparagraph (B), by striking  
19           “505(j).” and inserting the following: “505(j)  
20           or under an abbreviated new drug application  
21           pursuant to regulations in effect prior to imple-  
22           mentation of the Drug Price Competition and  
23           Patent Term Restoration Act of 1984, or a  
24           product approved under an application under  
25           section 507 that is abbreviated.”

1       (b) FEE AMOUNTS.—Section 736(b) (21 U.S.C.  
2 379h(b)) is amended to read as follows:

3       “(b) FEE AMOUNTS.—Except as provided in sub-  
4 sections (c), (d), (f), and (g), the fees required under sub-  
5 section (a) shall be determined and assessed as follows:

6           “(1) APPLICATION FEE.—The application fee  
7 under subsection (a)(1)(A)(i) shall be \$250,704 in  
8 fiscal year 1998, \$256,338 in fiscal years 1999 and  
9 2000, \$267,606 in fiscal year 2001, and \$258,451  
10 in fiscal year 2002.

11          “(2) SUPPLEMENT FEE.—The supplement fee  
12 under subsection (a)(1)(A)(ii) shall be \$125,352 in  
13 fiscal year 1998, \$128,169 in fiscal years 1999 and  
14 2000, \$133,803 in fiscal year 2001, and \$129,226  
15 in fiscal year 2002.

16          “(3) FEE REVENUES FOR ESTABLISHMENT  
17 FEES.—The total fee revenues to be collected in es-  
18 tablishment fees under subsection (a)(2) shall be  
19 \$35,600,000 in fiscal year 1998, \$36,400,000 in fis-  
20 cal years 1999 and 2000, \$38,000,000 in fiscal year  
21 2001, and \$36,700,000 in fiscal year 2002.

22          “(4) TOTAL FEE REVENUES FOR PRODUCT  
23 FEES.—The total fee revenues to be collected in  
24 product fees under subsection (a)(3) in a fiscal year  
25 shall be equal to the total fee revenues collected for

1 establishment fees under subsection (a)(2) in that  
 2 fiscal year.”.

3 ~~(c) INCREASES AND ADJUSTMENTS.—Section 736(c)~~  
 4 ~~(21 U.S.C. 379h(c)) is amended—~~

5 (1) in the subsection heading, by striking “IN-  
 6 CREASES AND”;

7 (2) in paragraph (1)—

8 (A) by striking “(1) REVENUE” and all  
 9 that follows through “increased by the Sec-  
 10 retary” and inserting the following: “(1) INFLA-  
 11 TION ADJUSTMENT.—The fees and total fee  
 12 revenues established in subsection (b) shall be  
 13 adjusted by the Secretary”;

14 (B) in subparagraph (A), by striking “in-  
 15 crease” and inserting “change”;

16 (C) in subparagraph (B), by striking “in-  
 17 crease” and inserting “change”; and

18 (D) by adding at the end the following  
 19 flush sentence:

20 “The adjustment made each fiscal year by this sub-  
 21 section will be added on a compounded basis to the  
 22 sum of all adjustments made each fiscal year after  
 23 fiscal year 1997 under this provision.”;

24 (3) in paragraph (2), by striking “October 1,  
 25 1992,” and all that follows through “such schedule.”

1 and inserting the following: “September 30, 1997,  
 2 adjust the establishment and product fees described  
 3 in subsection (b) so that the revenues collected from  
 4 each such fee category shall be set to be equal to the  
 5 revenues collected from the application and supple-  
 6 ment fee category.”; and

7 (4) in paragraph (3), by striking “paragraph  
 8 (2)” and inserting “this subsection”.

9 (d) FEE WAIVER OR REDUCTION.—Section 736(d)  
 10 (~~21 U.S.C. 379h(d)~~) is amended—

11 (1) by redesignating paragraphs (1), (2), (3),  
 12 and (4) as subparagraphs (A), (B), (C), and (D), re-  
 13 spectively and indenting appropriately;

14 (2) by striking “The Secretary shall grant a”  
 15 and all that follows through “finds that—” and in-  
 16 serting the following:

17 “(1) IN GENERAL.—The Secretary shall grant a  
 18 waiver from or a reduction of 1 or more fees under  
 19 subsection (a) where the Secretary finds that—”

20 (3) in subparagraph (C) (as so redesignated by  
 21 paragraph (1)); by striking “; or” and inserting a  
 22 comma;

23 (4) in subparagraph (D) (as so redesignated by  
 24 paragraph (1)); by striking the period and inserting  
 25 “; and”;

1           (5) by inserting after subparagraph (D) (as so  
2 redesignated by paragraph (1)) the following:

3           “~~(E)~~ the applicant is a small business sub-  
4 mitting its first human drug application to the  
5 Secretary for review.”; and

6           (6) by striking “In making the finding in para-  
7 graph (3),” and all that follows through “standard  
8 costs.” inserting the following:

9           “~~(2)~~ USE OF STANDARD COSTS.—In making the  
10 finding in subparagraph (C), the Secretary may use  
11 standard costs.

12           “~~(3)~~ RULES RELATING TO SMALL BUSI-  
13 NESSES.—

14           “~~(A)~~ DEFINITION.—For the purpose of  
15 paragraph (1)(E), a small business is an entity  
16 that has fewer than 500 employees, including  
17 employees of affiliates.

18           “~~(B)~~ WAIVER OF APPLICATION FEE.—The  
19 Secretary shall waive under paragraph (1)(E),  
20 the application fee for the first human drug ap-  
21 plication that a small business or its affiliate  
22 submits to the Secretary for review. After a  
23 small business or its affiliate is granted such a  
24 waiver, the small business or its affiliate shall  
25 pay—

1 “(i) application fees for all subsequent  
 2 human drug applications submitted to the  
 3 Secretary for review in the same manner  
 4 as an entity that does not qualify as a  
 5 small business; and

6 “(ii) all supplement fees for all sup-  
 7 plements to human drug applications sub-  
 8 mitted to the Secretary for review in the  
 9 same manner as an entity that does not  
 10 qualify as a small business.”.

11 (e) ASSESSMENT OF FEES.—Section 736(f)(1) (21  
 12 U.S.C. 379g(f)(1)) is amended—

13 (1) by striking “fiscal year 1993” and inserting  
 14 “fiscal year 1997”; and

15 (2) by striking “fiscal year 1992” and inserting  
 16 “fiscal year 1997 (excluding the amount of fees ap-  
 17 propriated for such fiscal year)”.

18 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-  
 19 tion 736(g) (21 U.S.C. 379g(g)) is amended—

20 (1) in paragraph (1), by adding at the end the  
 21 following: “Such sums as may be necessary may be  
 22 transferred from the Food and Drug Administration  
 23 salaries and expenses appropriation account without  
 24 fiscal year limitation to such appropriation account  
 25 for salaries and expenses with such fiscal year limi-

tation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of subsection 735(6).”;

(2) in paragraph (2)—

(A) in subparagraph (A), by striking “Acts” and inserting “Acts, or otherwise made available for obligation,”; and

(B) in subparagraph (B), by striking “over such costs for fiscal year 1992” and inserting “over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997”; and

(3) by striking paragraph (3) and inserting the following:

“(3) AUTHORIZATION OF APPROPRIATIONS.—

There is authorized to be appropriated for fees under this section—

“(A) \$106,800,000 for fiscal year 1998,

“(B) \$109,200,000 for fiscal year 1999,

“(C) \$109,200,000 for fiscal year 2000,

“(D) \$114,000,000 for fiscal year 2001,

and

“(E) \$110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the



1 total amounts collected by application, supplement,  
 2 establishment, and products fees.”.

3 ~~(g) REQUIREMENT FOR WRITTEN REQUESTS FOR~~  
 4 ~~WAIVERS AND FEES.—Section 736 (21 U.S.C. 379h) is~~  
 5 amended by—

6 (1) redesignating subsection (i) as subsection  
 7 (j); and

8 (2) by inserting after subsection (h) the follow-  
 9 ing:

10 “(i) WRITTEN REQUESTS FOR WAIVERS AND RE-  
 11 FUNDS.—To qualify for consideration for a waiver under  
 12 subsection (d), or for a refund of any fee collected in ac-  
 13 cordance with subsection (a), a person must submit to the  
 14 Secretary a written request for such waiver or refund not  
 15 later than 180 days after such fee is due. Any requests  
 16 for waivers, refunds, or exceptions must be submitted in  
 17 writing to the Secretary within 1 year after the date of  
 18 enactment of this subsection.”.

19 **SEC. 705. ANNUAL REPORTS.**

20 (a) FIRST REPORT.—Not later than 60 days after the  
 21 end of each fiscal year during which fees are collected  
 22 under part 2 of subchapter C of chapter VII of the Federal  
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.),  
 24 the Secretary of Health and Human Services shall prepare  
 25 and submit to the Committee on Commerce of the House

1 of Representatives and the Committee on Labor and  
 2 Human Resources of the Senate a report concerning the  
 3 progress of the Food and Drug Administration in achiev-  
 4 ing the goals identified in the letter described in section  
 5 702(4) during such fiscal year and the future plans of the  
 6 Food and Drug Administration for meeting the goals.

7       (b) **SECOND REPORT.**—Not later than 120 days after  
 8 the end of each fiscal year during which fees are collected  
 9 under the part described in subsection (a), the Secretary  
 10 of Health and Human Services shall prepare and submit  
 11 to the Committee on Commerce of the House of Rep-  
 12 resentatives and the Committee on Labor and Human Re-  
 13 sources of the Senate a report on the implementation of  
 14 the authority for such fees during such fiscal year and  
 15 the use, by the Food and Drug Administration, of the fees  
 16 collected during such fiscal year for which the report is  
 17 made.

18 **SEC. 706. EFFECTIVE DATE.**

19       The amendments made by this title shall take effect  
 20 October 1, 1997.

21 **SEC. 707. TERMINATION OF EFFECTIVENESS.**

22       The amendments made by sections 703 and 704  
 23 cease to be effective October 1, 2002 and section 4 ceases  
 24 to be effective 120 days after such date.

1       **TITLE VIII—MISCELLANEOUS**

2       **SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

3           Section 510(i) (21 U.S.C. 360(i)) is amended to read  
4 as follows:

5           “(i)(1) Any establishment within any foreign country  
6 engaged in the manufacture, preparation, propagation,  
7 compounding, or processing of a drug or drugs or a device  
8 or devices that are imported or offered for the import into  
9 the United States shall register with the Secretary the  
10 name and place of business of the establishment and the  
11 name of the United States agent for the establishment.

12          “(2) The establishment shall also provide the infor-  
13 mation required by subsection (j).

14          “(3) The Secretary is authorized to enter into cooper-  
15 ative arrangements with foreign countries to ensure that  
16 adequate and effective means are available for purposes  
17 of determining, from time to time, whether drugs or de-  
18 vices manufactured, prepared, propagated, compounded,  
19 or processed in an establishment in paragraph (1), if im-  
20 ported or offered for import into the United States, shall  
21 be refused admission on any of the grounds set forth in  
22 section 801(a) of this Act.

1 **SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIRE-**  
 2 **MENTS.**

3 (a) **PRESCRIPTION DRUGS.**—Section 503(b)(4) (21  
 4 U.S.C. 353(b)(4)) is amended to read as follows:

5 “(4)(A) A drug which is subject to paragraph (1)  
 6 shall be deemed to be misbranded if at any time prior to  
 7 dispensing the label of the drug fails to bear, at a mini-  
 8 mum, the symbol ‘Rx only.’”

9 “(B) A drug to which paragraph (1) does not apply  
 10 shall be deemed to be misbranded if at any time prior to  
 11 dispensing the label of the drug bears the symbol described  
 12 in subparagraph (B).

13 (b) **MISBRANDED DRUG.**—Section 502(d) (21 U.S.C.  
 14 352(d)) is repealed.

15 **SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.**

16 Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amend-  
 17 ed—

18 (1) in paragraph (1), in the fifth sentence, by  
 19 striking “paragraphs (1) and (2) of section 801(e)”  
 20 and inserting “subparagraphs (A) and (B) of section  
 21 801(e)(1)”; and

22 (2) by inserting after the fifth sentence the fol-  
 23 lowing: “Any person seeking to export an imported  
 24 article pursuant to any of the provisions of this sub-  
 25 section shall establish that the article was intended  
 26 for export at the time the article entered commerce.”

1 **SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PRO-**  
 2 **GRAM.**

3 Chapter IX (21 U.S.C. 391 et seq.), as amended by  
 4 section 206, is further amended by adding at the end the  
 5 following:

6 **“SEC. 908. RESEARCH TRAINING AWARD PROGRAM.**

7 “(a) IN GENERAL.—The Secretary, acting through  
 8 the Commissioner of Food and Drugs, may, directly or  
 9 through grants, contracts, or cooperative agreements, con-  
 10 duct and support research training in regulatory scientific  
 11 programs by predoctoral and postdoctoral scientists and  
 12 physicians, including the use of fellowships.

13 “(b) LIMITATION ON PARTICIPATION.—A recipient of  
 14 a fellowship under subsection (a) may not be an employee  
 15 of the Federal Government.

16 “(c) SPECIAL RULE.—The Secretary, acting through  
 17 the Commissioner of Food and Drugs, may support the  
 18 provision of assistance for fellowships through a Coopera-  
 19 tive Research and Development Agreement.”.

20 **SEC. 805. ENFORCEMENT AUTHORITY FOR SPECIAL CON-**  
 21 **TROLS.**

22 (a) ADULTERATED PROVISIONS.—Section 501(e) as  
 23 amended by section 205, is amended by striking subpara-  
 24 graph (1) and inserting the following: “(1) If it is, or  
 25 purports to be or is represented as, a device which is sub-  
 26 ject to a performance standard or a special control estab-

1 lished under section 514, unless such device is in all re-  
 2 spects in conformity with such standard or special con-  
 3 trol.”.

4 (b) MISBRANDED PROVISIONS.—Section 502(s) (21  
 5 U.S.C. 352(s)) is amended to read as follows:

6 “(s) If it is a device subject to a performance stand-  
 7 ard or a special control established or recognized under  
 8 section 514, unless the device bears such labeling as may  
 9 be prescribed in such standard or special control.”.

10 **SEC. 806. DEVICE SAMPLES.**

11 (a) RECALL AUTHORITY.—

12 (1) IN GENERAL.—Section 518(c)(2) (21  
 13 U.S.C. 360h(c)(2)) is amended by adding at the end  
 14 the following:

15 “(C) If the Secretary issues an amended order under  
 16 subparagraph (A), the Secretary may require the person  
 17 subject to the order to submit samples of such device and  
 18 of components of the device as the Secretary may reason-  
 19 ably require, except that where the submission of such  
 20 samples is impracticable or unduly burdensome, the re-  
 21 quirement of this subparagraph may be met by the sub-  
 22 mission of complete information concerning the location  
 23 of 1 or more such devices readily available for examination  
 24 and testing.”.

1           (2)       TECHNICAL        AMENDMENT.—Section  
 2       518(e)(2)(A)) is amended by striking “subpara-  
 3       graphs (B) and (C)” and inserting “subparagraph  
 4       (B)”.

5       (b) RECORDS AND REPORTS ON DEVICES.—Section  
 6       519(a) (21 U.S.C. 360(a)) is amended—

7           (1) in paragraph (8), by striking “; and” and  
 8       inserting a semicolon;

9           (2) in paragraph (9), by striking “made.” and  
 10       inserting “made; and”;

11          (3) by inserting after paragraph (9) the follow-  
 12       ing:

13           “(10) may reasonably require a manufacturer,  
 14       importer, or distributor to submit samples of a de-  
 15       vice and of components of the device that may have  
 16       caused or contributed to a death or serious injury;  
 17       except that where the submission of such samples is  
 18       impracticable or unduly burdensome, the require-  
 19       ment of this paragraph may be met by the submis-  
 20       sion of complete information concerning the location  
 21       of 1 or more such devices readily available for exam-  
 22       ination and testing.”.

23   **SEC. 807. INTERSTATE COMMERCE.**

24       (a) FINDINGS.—Congress finds that—

1           (1) in order to make effective the regulation of  
 2 interstate commerce involving devices, foods, drugs,  
 3 and cosmetics, it is necessary to impose equivalent  
 4 requirements on intrastate commerce involving adul-  
 5 terated and misbranded devices, foods, drugs, and  
 6 cosmetics as imposed on interstate commerce in such  
 7 articles;

8           (2) without the presumption of a connection  
 9 with interstate commerce, intrastate commerce in-  
 10 volving adulterated and misbranded devices, foods,  
 11 drugs, and cosmetics would discriminate against and  
 12 depress interstate commerce in devices, foods, drugs,  
 13 and cosmetics, and adversely burden, obstruct, and  
 14 affect such interstate commerce; and

15           (3) transactions involving adulterated and mis-  
 16 branded devices, foods, drugs, and cosmetics con-  
 17 stitute a class of activities that have a deleterious ef-  
 18 fect on the public health and welfare.

19           (b) DEFINITION.—Section 201(b) (21 U.S.C. 321(b))  
 20 is amended—

21           (1) by striking “and (2) commerce” and insert-  
 22 ing “(2) commerce”;

23           (2) by inserting before the period the following:  
 24           “; and (3) commerce involving any article or class of



1 activities that directly or indirectly affects interstate  
 2 commerce pursuant to section 709”.

3 (c) SEIZURE.—Section 304(a)(2)(D) (21 U.S.C.  
 4 304(a)(2)(D)) is amended to read as follows: “(D) Any  
 5 adulterated or misbranded device, food, drug, or cos-  
 6 metic.”.

7 (d) PRESUMPTION.—Section 709 (21 U.S.C. 379a)  
 8 is amended by striking “a device” and inserting “a device,  
 9 food, drug, or cosmetic”.

#### 10 **SECTION 1. SHORT TITLE.**

11 *This Act may be cited as the “Food and Drug Admin-  
 12 istration Modernization and Accountability Act of 1997”.*

#### 13 **SEC. 2. TABLE OF CONTENTS.**

14 *The table of contents for this Act is as follows:*

*Sec. 1. Short title.*

*Sec. 2. Table of contents.*

*Sec. 3. References.*

#### **TITLE I—IMPROVING PATIENT ACCESS**

*Sec. 101. Mission of the Food and Drug Administration.*

*Sec. 102. Expedited access to investigational therapies.*

*Sec. 103. Expanded humanitarian use of devices.*

#### **TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES**

*Sec. 201. Interagency collaboration.*

*Sec. 202. Sense of the committee regarding mutual recognition agreements and  
 global harmonization efforts.*

*Sec. 203. Contracts for expert review.*

*Sec. 204. Accredited-party reviews.*

*Sec. 205. Device performance standards.*

#### **TITLE III—IMPROVING COLLABORATION AND COMMUNICATION**

*Sec. 301. Collaborative determinations of device data requirements.*

*Sec. 302. Collaborative review process.*

#### **TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES**

*Sec. 401. Policy statements.*

- Sec. 402. Product classification.*
- Sec. 403. Use of data relating to premarket approval.*
- Sec. 404. Consideration of labeling claims for product review.*
- Sec. 405. Definition of a day for purposes of product review.*
- Sec. 406. Certainty of review timeframes.*
- Sec. 407. Limitations on initial classification determinations.*
- Sec. 408. Clarification with respect to a general use and specific use of a device.*
- Sec. 409. Clarification of the number of required clinical investigations for approval.*
- Sec. 410. Prohibited acts.*

#### *TITLE V—IMPROVING ACCOUNTABILITY*

- Sec. 501. Agency plan for statutory compliance and annual report.*

#### *TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES*

- Sec. 601. Minor modifications.*
- Sec. 602. Environmental impact review.*
- Sec. 603. Exemption of certain classes of devices from premarket notification requirement.*
- Sec. 604. Evaluation of automatic class III designation.*
- Sec. 605. Secretary's discretion to track devices.*
- Sec. 606. Secretary's discretion to conduct postmarket surveillance.*
- Sec. 607. Reporting.*
- Sec. 608. Pilot and small-scale manufacture.*
- Sec. 609. Requirements for radiopharmaceuticals.*
- Sec. 610. Modernization of regulation of biological products.*
- Sec. 611. Approval of supplemental applications for approved products.*
- Sec. 612. Health care economic information.*
- Sec. 613. Expediting study and approval of fast track drugs.*
- Sec. 614. Manufacturing changes for drugs and biologics.*
- Sec. 615. Data requirements for drugs and biologics.*
- Sec. 616. Food contact substances.*
- Sec. 617. Health claims for food products.*
- Sec. 618. Pediatric studies marketing exclusivity.*
- Sec. 619. Positron emission tomography.*

#### *TITLE VII—FEES RELATING TO DRUGS*

- Sec. 701. Short title.*
- Sec. 702. Findings.*
- Sec. 703. Definitions.*
- Sec. 704. Authority to assess and use drug fees.*
- Sec. 705. Annual reports.*
- Sec. 706. Effective date.*
- Sec. 707. Termination of effectiveness.*

#### *TITLE VIII—MISCELLANEOUS*

- Sec. 801. Registration of foreign establishments.*
- Sec. 802. Elimination of certain labeling requirements.*
- Sec. 803. Clarification of seizure authority.*
- Sec. 804. Intramural research training award program.*
- Sec. 805. Device samples.*
- Sec. 806. Interstate commerce.*

*Sec. 807. National uniformity for nonprescription drugs and cosmetics.*

*Sec. 808. Information program on clinical trials for serious or life-threatening diseases.*

*Sec. 809. Application of Federal law to the practice of pharmacy compounding.*

**1 SEC. 3. REFERENCES.**

2 *Except as otherwise expressly provided, wherever in*  
 3 *this Act an amendment or repeal is expressed in terms of*  
 4 *an amendment to, or repeal of, a section or other provision,*  
 5 *the reference shall be considered to be made to a section or*  
 6 *other provision of the Federal Food, Drug, and Cosmetic*  
 7 *Act (21 U.S.C. 321 et seq.).*

8 ***TITLE I—IMPROVING PATIENT***  
 9 ***ACCESS***

10 ***SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRA-***  
 11 ***TION.***

12 *Section 903 (21 U.S.C. 393) is amended—*

13 *(1) by redesignating subsections (b) and (c) as*  
 14 *subsections (c) and (d), respectively; and*

15 *(2) by inserting after subsection (a) the follow-*  
 16 *ing:*

17 *“(b) MISSION.—*

18 *“(1) IN GENERAL.—The Administration shall*  
 19 *protect the public health by ensuring that—*

20 *“(A) foods are safe, wholesome, sanitary,*  
 21 *and properly labeled;*

22 *“(B) human and veterinary drugs are safe*  
 23 *and effective;*

1                   “(C) *there is reasonable assurance of safety*  
 2                   *and effectiveness of devices intended for human*  
 3                   *use;*

4                   “(D) *cosmetics are safe; and*

5                   “(E) *public health and safety are protected*  
 6                   *from electronic product radiation.*

7                   “(2) *SPECIAL RULES.—The Administration shall*  
 8                   *promptly and efficiently review clinical research and*  
 9                   *take appropriate action on the marketing of regulated*  
 10                   *products in a manner that does not unduly impede*  
 11                   *innovation or product availability. The Administra-*  
 12                   *tion shall participate with other countries to reduce*  
 13                   *the burden of regulation, to harmonize regulatory re-*  
 14                   *quirements, and to achieve appropriate reciprocal ar-*  
 15                   *rangements with other countries.”.*

16 **SEC. 102. EXPEDITED ACCESS TO INVESTIGATIONAL**  
 17 **THERAPIES.**

18                   *Chapter V (21 U.S.C. 351 et seq.) is amended by add-*  
 19                   *ing at the end the following:*

20                   “**SUBCHAPTER D—UNAPPROVED THERAPIES AND**  
 21                   **DIAGNOSTICS**

22 “**SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES**  
 23 **AND DIAGNOSTICS.**

24                   “(a) *IN GENERAL.—Any person, acting through a phy-*  
 25                   *sician licensed in accordance with State law, may request*

1 *from a manufacturer or distributor, and any manufacturer*  
2 *or distributor may provide to a person after compliance*  
3 *with the provisions of this section, an investigational drug*  
4 *(including a biological product) or investigational device*  
5 *for the diagnosis, monitoring, or treatment of a serious dis-*  
6 *ease or condition, or any other disease or condition des-*  
7 *ignated by the Secretary as appropriate for expanded access*  
8 *under this section if—*

9           “(1) *the licensed physician determines that the*  
10       *person has no comparable or satisfactory alternative*  
11       *therapy available to diagnose, monitor, or treat the*  
12       *disease or condition involved;*

13           “(2) *the licensed physician determines that the*  
14       *risk to the person from the investigational drug or in-*  
15       *vestigational device is not greater than the risk from*  
16       *the disease or condition;*

17           “(3) *the Secretary determines that an exemption*  
18       *for the investigational drug or investigational device*  
19       *is in effect under a regulation promulgated pursuant*  
20       *to section 505(i) or 520(g) and the sponsor of the*  
21       *drug or device and investigators comply with such*  
22       *regulation;*

23           “(4) *the Secretary determines that the manufac-*  
24       *turer of the investigational drug or investigational de-*

1       *vice is actively pursuing marketing approval with*  
2       *due diligence;*

3               “(5) the Secretary determines that expanded ac-  
4       *cess to the investigational drug or investigational de-*  
5       *vice will not interfere with adequate enrollment of pa-*  
6       *tients by the investigator in the ongoing clinical in-*  
7       *vestigation of the investigational drug or investiga-*  
8       *tional device authorized under section 505(i) or*  
9       *520(g); and*

10              “(6) the Secretary determines that there is suffi-  
11       *cient evidence of safety and effectiveness to support*  
12       *the expanded use of the investigational drug or inves-*  
13       *tigational device in accordance with this section.*

14              “(b) *PROTOCOLS.*—A manufacturer or distributor may  
15       *submit to the Secretary 1 or more expanded access protocols*  
16       *covering expanded access use of a drug or device described*  
17       *in subsection (a). The protocols shall be subject to the provi-*  
18       *sions of section 505(i) or 520(g) and may include any form*  
19       *of use of the drug or device outside a clinical investigation,*  
20       *prior to approval of the drug or device for marketing, in-*  
21       *cluding protocols for treatment use, emergency use, or un-*  
22       *controlled trials, and single patient protocols. If the request*  
23       *for expanded access to an investigational drug or investiga-*  
24       *tional device is intended for a single patient only, the Sec-*  
25       *retary may waive the requirements of paragraphs (3) and*

1 (4) of subsection (a) and accept a submission under section  
 2 505(i) or 520(g) for an exemption for the investigational  
 3 drug or investigational device for the single patient use. In  
 4 the case of an emergency that does not allow sufficient time  
 5 for a submission under section 505(i) or 520(g), the Sec-  
 6 retary may, prior to the submission, authorize the shipment  
 7 of the investigational drug or investigational device for a  
 8 single patient use.

9 “(c) NOTIFICATION OF AVAILABILITY.—The Secretary  
 10 shall inform national, State, and local medical associations  
 11 and societies, voluntary health associations, and other ap-  
 12 propriate persons about the availability of an investiga-  
 13 tional drug or investigational device under expanded access  
 14 protocols submitted under this section, except that this sub-  
 15 section shall not apply to expanded access protocols for sin-  
 16 gle patient use.

17 “(d) TERMINATION.—The Secretary may at anytime  
 18 terminate expanded access provided under subsection (a) for  
 19 an investigational drug or investigational device if the re-  
 20 quirements under this section are no longer met.”.

21 **SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.**

22 Section 520(m) (21 U.S.C. 360j(m)) is amended—

23 (1) in paragraph (2), by adding at the end the  
 24 following flush sentences:

1 *“The request shall be in the form of an application submit-*  
 2 *ted to the Secretary. Not later than 60 days after the date*  
 3 *of the receipt of the application, the Secretary shall issue*  
 4 *an order approving or denying the application.”;*

5 *(2) in paragraph (4)—*

6 *(A) in subparagraph (B), by inserting after*  
 7 *“(2)(A)” the following: “, unless a physician de-*  
 8 *termines that waiting for such an approval from*  
 9 *an institutional review committee will cause*  
 10 *harm or death to a patient, and makes a good*  
 11 *faith effort to obtain the approval, and does not*  
 12 *receive a timely response from an institutional*  
 13 *review committee on the request of the physician*  
 14 *for approval to use the device for such treatment*  
 15 *or diagnosis”;* and

16 *(B) by adding at the end the following flush*  
 17 *sentences:*

18 *“In a case in which a physician described in subparagraph*  
 19 *(B) uses a device without an approval from an institutional*  
 20 *review committee, the physician shall, after the use of the*  
 21 *device, notify the chairperson of the institutional review*  
 22 *committee of such use. Such notification shall include the*  
 23 *identification of the patient involved, the date on which the*  
 24 *device was used, and the reason for the use.”;* and



1           (3) by striking paragraph (5) and inserting the  
2       *following:*

3           “(5) *The Secretary may require a person granted an*  
4 *exemption under paragraph (2) to demonstrate continued*  
5 *compliance with the requirements of this subsection if the*  
6 *Secretary believes such demonstration to be necessary to*  
7 *protect the public health or if the Secretary has reason to*  
8 *believe that the criteria for the exemption are no longer*  
9 *met.”.*

10       ***TITLE II—INCREASING ACCESS***  
11       ***TO EXPERTISE AND RESOURCES***

12       ***SEC. 201. INTERAGENCY COLLABORATION.***

13           *Section 903(b) (21 U.S.C. 393(b)), as added by section*  
14 *101(2), is amended by adding at the end the following:*

15           “(3) *INTERAGENCY COLLABORATION.—The Sec-*  
16 *retary shall implement programs and policies that*  
17 *will foster collaboration between the Administration,*  
18 *the National Institutes of Health, and other science-*  
19 *based Federal agencies, to enhance the scientific and*  
20 *technical expertise available to the Secretary in the*  
21 *conduct of the duties of the Secretary with respect to*  
22 *the development, clinical investigation, evaluation,*  
23 *and postmarket monitoring of emerging medical*  
24 *therapies, including complementary therapies, and*  
25 *advances in nutrition and food science.”.*

1 **SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL**  
2 **RECOGNITION AGREEMENTS AND GLOBAL**  
3 **HARMONIZATION EFFORTS.**

4 *It is the sense of the Committee on Labor and Human*  
5 *Resources of the Senate that—*

6 *(1) the Secretary of Health and Human Services*  
7 *should support the Office of the United States Trade*  
8 *Representative, in consultation with the Secretary of*  
9 *Commerce, in efforts to move toward the acceptance*  
10 *of mutual recognition agreements relating to the regu-*  
11 *lation of drugs, biological products, devices, foods,*  
12 *food additives, and color additives, and the regulation*  
13 *of good manufacturing practices, between the Euro-*  
14 *pean Union and the United States;*

15 *(2) the Secretary of Health and Human Services*  
16 *should regularly participate in meetings with rep-*  
17 *resentatives of other foreign governments to discuss*  
18 *and reach agreement on methods and approaches to*  
19 *harmonize regulatory requirements; and*

20 *(3) the Office of International Relations of the*  
21 *Department of Health and Human Services (as estab-*  
22 *lished under section 803 of the Federal Food, Drug,*  
23 *and Cosmetic Act (21 U.S.C. 383)) should have the*  
24 *responsibility of ensuring that the process of harmo-*  
25 *nizing international regulatory requirements is con-*  
26 *tinuous.*

1 **SEC. 203. CONTRACTS FOR EXPERT REVIEW.**

2 *Chapter IX (21 U.S.C. 391 et seq.) is amended by add-*  
3 *ing at the end the following:*

4 **“SEC. 906. CONTRACTS FOR EXPERT REVIEW.**

5 **“(a) IN GENERAL.—**

6 *“(1) AUTHORITY.—The Secretary may enter into*  
7 *a contract with any organization or any individual*  
8 *(who is not an employee of the Department) with ex-*  
9 *pertise in a relevant discipline, to review, evaluate,*  
10 *and make recommendations to the Secretary on part*  
11 *or all of any application or submission (including a*  
12 *petition, notification, and any other similar form of*  
13 *request) made under this Act for the approval or clas-*  
14 *sification of an article or made under section 351(a)*  
15 *of the Public Health Service Act (42 U.S.C. 262(a))*  
16 *with respect to a biological product. Any such con-*  
17 *tract shall be subject to the requirements of section*  
18 *708 relating to the confidentiality of information.*

19 **“(2) INCREASED EFFICIENCY AND EXPERTISE**  
20 **THROUGH CONTRACTS.—***The Secretary shall use the*  
21 *authority granted in paragraph (1) whenever the Sec-*  
22 *retary determines that a contract described in para-*  
23 *graph (1) will improve the timeliness or quality of the*  
24 *review of an application or submission described in*  
25 *paragraph (1). Such improvement may include pro-*  
26 *viding the Secretary increased scientific or technical*

1 *expertise that is necessary to review or evaluate new*  
 2 *therapies and technologies.*

3 *“(b) REVIEW OF EXPERT REVIEW.—*

4 *“(1) IN GENERAL.—Subject to paragraph (2), the*  
 5 *official of the Food and Drug Administration respon-*  
 6 *sible for any matter for which expert review is used*  
 7 *pursuant to subsection (a) shall review the rec-*  
 8 *ommendations of the organization or individual who*  
 9 *conducted the expert review and shall make a final*  
 10 *decision regarding the matter within 60 days after re-*  
 11 *ceiving the recommendations.*

12 *“(2) LIMITATION.—A final decision under para-*  
 13 *graph (1) shall be made within the applicable pre-*  
 14 *scribed time period for review of the matter as set*  
 15 *forth in this Act or in the Public Health Service Act*  
 16 *(42 U.S.C. 201 et seq.).*

17 *“(3) AUTHORITY OF SECRETARY.—Notwithstand-*  
 18 *ing subsection (a), the Secretary shall retain full au-*  
 19 *thority to make determinations with respect to the ap-*  
 20 *proval or disapproval of an article under this Act, the*  
 21 *approval or disapproval of a biologics license with re-*  
 22 *spect to a biological product under section 351(a) of*  
 23 *the Public Health Service Act, or the classification of*  
 24 *an article as a device under section 513(f)(1).”.*

1 **SEC. 204. ACCREDITED-PARTY REVIEWS.**

2 *Subchapter A of chapter V (21 U.S.C. 351 et seq.) is*  
 3 *amended by adding at the end the following:*

4 **“SEC. 523. ACCREDITED-PARTY PARTICIPATION.**

5 **“(a) ACCREDITATION.—**

6 **“(1) IN GENERAL.—***Not later than 1 year after*  
 7 *the date of enactment of this section, the Secretary*  
 8 *shall accredit entities or individuals who are not em-*  
 9 *ployees of the Federal Government, to review reports*  
 10 *made to the Secretary under section 510(k) for devices*  
 11 *and make recommendations to the Secretary regard-*  
 12 *ing the initial classification of such devices under sec-*  
 13 *tion 513(f)(1), except that this paragraph shall not*  
 14 *apply to reports made to the Secretary under section*  
 15 *510(k) for devices that are—*

16 **“(A) life-supporting;**

17 **“(B) life sustaining; or**

18 **“(C) intended for implantation in the**  
 19 **human body for a period of over 1 year.**

20 **“(2) SPECIAL RULE.—***The Secretary shall have*  
 21 *the discretion to accredit entities or individuals who*  
 22 *are not employees of the Federal Government—*

23 **“(A) to review reports made to the Sec-**  
 24 **retary under section 510(k) for devices described**  
 25 **in subparagraphs (A) through (C) of paragraph**

1           (1), and make recommendations of initial classi-  
2           fication of such devices; or

3           “(B) to review applications for premarket  
4           approval for class III devices under section 515  
5           and make recommendations with respect to the  
6           approval or disapproval of such applications.

7           “(b) ACCREDITATION.—Within 180 days after the date  
8           of enactment of this section, the Secretary shall adopt meth-  
9           ods of accreditation that ensure that entities or individuals  
10          who conduct reviews and make recommendations under this  
11          section are qualified, properly trained, knowledgeable about  
12          handling confidential documents and information, and free  
13          of conflicts of interest. The Secretary shall publish the meth-  
14          ods of accreditation in the Federal Register on the adoption  
15          of the methods.

16          “(c) WITHDRAWAL OF ACCREDITATION.—The Sec-  
17          retary may suspend or withdraw the accreditation of any  
18          entity or individual accredited under this section, after pro-  
19          viding notice and an opportunity for an informal hearing,  
20          if such entity or individual acts in a manner that is sub-  
21          stantially not in compliance with the requirements estab-  
22          lished by the Secretary under subsection (b), including the  
23          failure to avoid conflicts of interest, the failure to protect  
24          confidentiality of information, or the failure to competently  
25          review premarket submissions for devices.

1       “(d) *SELECTION AND COMPENSATION.*—Subject to sub-  
2   section (a)(2), a person who intends to make a report de-  
3   scribed in subsection (a), or to submit an application de-  
4   scribed in subsection (a), to the Secretary shall have the  
5   option to select an accredited entity or individual to review  
6   such report or application. Upon the request by a person  
7   to have a report or application reviewed by an accredited  
8   entity or individual, the Secretary shall identify for the per-  
9   son no less than 2 accredited entities or individuals from  
10   whom the selection may be made. Compensation for an ac-  
11   credited entity or individual shall be determined by agree-  
12   ment between the accredited entity or individual and the  
13   person who engages the services of the accredited entity or  
14   individual and shall be paid by the person who engages  
15   such services.

16       “(e) *REVIEW BY SECRETARY.*—

17               “(1) *IN GENERAL.*—The Secretary shall require  
18   an accredited entity or individual, upon making a  
19   recommendation under this section with respect to an  
20   initial classification of a device or approval or dis-  
21   approval of an application for premarket approval, to  
22   notify the Secretary in writing of the reasons for such  
23   recommendation.

24               “(2) *TIME PERIOD FOR REVIEW.*—

1           “(A) *INITIAL CLASSIFICATION.*—Not later  
2           than 30 days after the date on which the Sec-  
3           retary is notified under paragraph (1) by an ac-  
4           credited entity or individual with respect to a  
5           recommendation of an initial classification of a  
6           device, the Secretary shall make a determination  
7           with respect to the initial classification.

8           “(B) *PREMARKET APPROVAL.*—Not later  
9           than 60 days after the date on which the Sec-  
10          retary is notified under paragraph (1) by an ac-  
11          credited entity or individual with respect to a  
12          recommendation of an approval or disapproval  
13          of an application for a device, the Secretary  
14          shall make a determination with respect to the  
15          approval or disapproval.

16          “(3) *SPECIAL RULE.*—The Secretary may change  
17          the initial classification under section 513(f)(1), or  
18          the approval or disapproval of the application under  
19          section 515(d), that is recommended by the accredited  
20          entity or individual under this section, and in such  
21          case shall notify in writing the person making the re-  
22          port or application described in subsection (a) of the  
23          detailed reasons for the change.

24          “(f) *DURATION.*—The authority provided by this sec-  
25          tion terminates—



1           “(1) 5 years after the date on which the Sec-  
 2       retary notifies Congress that at least 2 persons accred-  
 3       ited under subsection (b) are available to review de-  
 4       vices for each of at least 70 percent of the generic  
 5       types of devices subject to review under subsection (a);  
 6       or

7           “(2) 4 years after the date on which the Sec-  
 8       retary notifies Congress that at least 35 percent of the  
 9       devices that are subject to review under subsection (a),  
 10      and that were the subject of final action by the Sec-  
 11      retary in the fiscal year preceding the date of such  
 12      notification, were reviewed by the Secretary under  
 13      subsection (e),  
 14      whichever occurs first.

15       “(g) REPORT.—

16           “(1) IN GENERAL.—Not later than 1 year after  
 17      the date of enactment of this section, the Secretary  
 18      shall contract with an independent research organiza-  
 19      tion to prepare and submit to the Secretary a written  
 20      report examining the use of accredited entities and  
 21      individuals to conduct reviews under this section. The  
 22      Secretary shall submit the report to Congress not later  
 23      than 6 months prior to the conclusion of the applica-  
 24      ble period described in subsection (f).

1           “(2) *CONTENTS.*—*The report by the independent*  
 2           *research organization described in paragraph (1)*  
 3           *shall identify the benefits or detriments to public and*  
 4           *patient health of using accredited entities and indi-*  
 5           *viduals to conduct such reviews, and shall summarize*  
 6           *all relevant data, including data on the review of ac-*  
 7           *credited entities and individuals (including data on*  
 8           *the review times, recommendations, and compensation*  
 9           *of the entities and individuals), and data on the re-*  
 10          *view of the Secretary (including data on the review*  
 11          *times, changes, and reasons for changes of the Sec-*  
 12          *retary).”.*

13 **SEC. 205. DEVICE PERFORMANCE STANDARDS.**

14          *(a) ALTERNATIVE PROCEDURE.*—*Section 514 (21*  
 15          *U.S.C. 360d) is amended by adding at the end the follow-*  
 16          *ing:*

17                                 *“Recognition of a Standard*

18          *“(c)(1)(A) In addition to establishing performance*  
 19          *standards under this section, the Secretary may, by publi-*  
 20          *cation in the Federal Register, recognize all or part of a*  
 21          *performance standard established by a nationally or inter-*  
 22          *nationally recognized standard development organization*  
 23          *for which a person may submit a declaration of conformity*  
 24          *in order to meet premarket submission requirements or*

1 *other requirements under this Act to which such standards*  
2 *are applicable.*

3       “(B) *If a person elects to use a performance standard*  
4 *recognized by the Secretary under subparagraph (A) to meet*  
5 *the requirements described in subparagraph (A), the person*  
6 *shall provide a declaration of conformity to the Secretary*  
7 *that certifies that the device is in conformity with such*  
8 *standard. A person may elect to use data, or information,*  
9 *other than data required by a standard recognized under*  
10 *subparagraph (A) to fulfill or satisfy any requirement*  
11 *under this Act.*

12       “(2) *The Secretary may withdraw such recognition of*  
13 *a performance standard through publication of a notice in*  
14 *the Federal Register that the Secretary will no longer recog-*  
15 *nize the standard, if the Secretary determines that the*  
16 *standard is no longer appropriate for meeting the require-*  
17 *ments under this Act.*

18       “(3)(A) *Subject to subparagraph (B), the Secretary*  
19 *shall accept a declaration of conformity that a device is in*  
20 *conformity with a standard recognized under paragraph (1)*  
21 *unless the Secretary finds—*

22               “(i) *that the data or information submitted to*  
23 *support such declaration does not demonstrate that*  
24 *the device is in conformity with the standard identi-*  
25 *fied in the declaration of conformity; or*

1           “(ii) that the standard identified in the declara-  
 2           tion of conformity is not applicable to the particular  
 3           device under review.

4           “(B) The Secretary may request, at any time, the data  
 5           or information relied on by the person to make a declara-  
 6           tion of conformity with respect to a standard recognized  
 7           under paragraph (1).

8           “(C) A person relying on a declaration of conformity  
 9           with respect to a standard recognized under paragraph (1)  
 10          shall maintain the data and information demonstrating  
 11          conformity of the device to the standard for a period of 2  
 12          years after the date of the classification or approval of the  
 13          device by the Secretary or a period equal to the expected  
 14          design life of the device, whichever is longer.”.

15          (b) SECTION 301.—Section 301 (21 U.S.C. 331) is  
 16          amended by adding at the end the following:

17           “(x) The falsification of a declaration of conformity  
 18          submitted under subsection (c) of section 514 or the failure  
 19          or refusal to provide data or information requested by the  
 20          Secretary under section 514(c)(3).”.

21          (c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e))  
 22          is amended—

23           (1) by striking “(e)” and inserting “(e)(1)”; and  
 24           (2) by inserting at the end the following:

1       “(2) If it is, declared to be, purports to be, or is rep-  
 2   resented as, a device that is in conformity with any per-  
 3   formance standard recognized under section 514(c) unless  
 4   such device is in all respects in conformity with such stand-  
 5   ard.”.

6   **TITLE III—IMPROVING COLLABO-**  
 7       **RATION AND COMMUNICA-**  
 8       **TION**

9   **SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE**  
 10       **DATA REQUIREMENTS.**

11       Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended  
 12   by adding at the end the following:

13       “(C)(i)(I) The Secretary, upon the written request of  
 14   any person intending to submit an application under sec-  
 15   tion 515, shall meet with such person to determine the type  
 16   of valid scientific evidence (within the meaning of subpara-  
 17   graphs (A) and (B)) that will be necessary to demonstrate  
 18   the effectiveness of a device for the conditions of use pro-  
 19   posed by such person, to support an approval of an applica-  
 20   tion. The written request shall include a detailed descrip-  
 21   tion of the device, a detailed description of the proposed con-  
 22   ditions of use of the device, and, if available, information  
 23   regarding the expected performance from the device. Within  
 24   30 days after such meeting, the Secretary shall specify in  
 25   writing the type of valid scientific evidence that will pro-

1 *vide a reasonable assurance that a device is effective under*  
2 *the conditions of use proposed by such person.*

3       “(II) *Any clinical data, including 1 or more well-con-*  
4 *trolled investigations, specified in writing by the Secretary*  
5 *for demonstrating a reasonable assurance of device effective-*  
6 *ness shall be specified as a result of a determination by*  
7 *the Secretary—*

8               “(aa) *that such data are necessary to establish*  
9 *device effectiveness; and*

10              “(bb) *that no other less burdensome means of*  
11 *evaluating device effectiveness is available that would*  
12 *have a reasonable likelihood of resulting in an ap-*  
13 *proval.*

14       “(ii) *The determination of the Secretary with respect*  
15 *to the specification of valid scientific evidence under clause*  
16 *(i) shall be binding upon the Secretary, unless—*

17              “(I) *such determination by the Secretary would*  
18 *be contrary to the public health; or*

19              “(II) *based on new information (other than the*  
20 *information reviewed by the Secretary in making*  
21 *such determination) obtained by the Secretary prior*  
22 *to the approval of an application for an investiga-*  
23 *tional device exemption under section 520(g), the Sec-*  
24 *retary finds that such determination is scientifically*  
25 *inappropriate.”.*

1 **SEC. 302. COLLABORATIVE REVIEW PROCESS.**

2 *Section 515(d) (21 U.S.C. 360e(d)) is amended—*

3 *(1) in paragraph (1)(A), by striking “paragraph*  
4 *(2) of this subsection” each place it appears and in-*  
5 *serting “paragraph (4)”;*

6 *(2) by redesignating paragraphs (2) and (3) as*  
7 *paragraphs (4) and (5), respectively; and*

8 *(3) by inserting after paragraph (1) the follow-*  
9 *ing:*

10 *“(2)(A)(i) The Secretary shall, upon the written re-*  
11 *quest of the applicant involved, meet with the applicant not*  
12 *later than 100 days after the receipt of an application, from*  
13 *the applicant, that has been filed as complete under sub-*  
14 *section (c), to discuss the review status of the application.*

15 *“(ii) If the application does not appear in a form that*  
16 *would require an approval under this subsection, the Sec-*  
17 *retary shall in writing, and prior to the meeting, provide*  
18 *to the applicant a description of any deficiencies in the ap-*  
19 *plication identified by the Secretary and identify the infor-*  
20 *mation (other than information the Secretary needs to make*  
21 *a finding under paragraph (4)(C)) that is required to bring*  
22 *the application into an approvable form.*

23 *“(iii) The Secretary and the applicant may, by mu-*  
24 *tual consent, establish a different schedule for a meeting re-*  
25 *quired under this paragraph.*

1       “(B) *The Secretary shall notify the applicant imme-*  
 2 *diately of any deficiency identified in the application that*  
 3 *was not described as a deficiency in the written description*  
 4 *provided by the Secretary under subparagraph (A).”.*

5       ***TITLE       IV—IMPROVING       CER-***  
 6       ***TAINTY       AND       CLARITY       OF***  
 7       ***RULES***

8       ***SEC. 401. POLICY STATEMENTS.***

9       *Section 701(a) (21 U.S.C. 371(a)) is amended—*  
 10       *(1) by striking “(a) The” and inserting “(a)(1)*  
 11 *The”; and*

12       *(2) by adding at the end the following:*

13       *“(2) Not later than February 27, 1999, the Secretary,*  
 14 *after evaluating the effectiveness of the Good Guidance*  
 15 *Practices document published in the Federal Register at 62*  
 16 *Fed. Reg. 8961, shall promulgate a regulation specifying*  
 17 *the policies and procedures of the Food and Drug Adminis-*  
 18 *tration for the development, issuance, and use of guidance*  
 19 *documents.”.*

20       ***SEC. 402. PRODUCT CLASSIFICATION.***

21       *Chapter VII (21 U.S.C. 371 et seq.) is amended by*  
 22 *adding at the end the following:*



1     “*SUBCHAPTER D—CLASSIFICATION OF PRODUCTS AND*  
2                     *ENVIRONMENTAL IMPACT REVIEWS*

3     “**SEC. 741. CLASSIFICATION OF PRODUCTS.**

4             “(a) *REQUEST.*—A person who submits an application  
5     or submission (including a petition, notification, and any  
6     other similar form of request) under this Act, may submit  
7     a request to the Secretary respecting the classification of  
8     an article (including an article that is a combination prod-  
9     uct subject to section 503(g)) as a drug, biological product,  
10    or device, or respecting the component of the Food and Drug  
11    Administration that will regulate the article. In submitting  
12    the request, the person shall recommend a classification for  
13    the article, or a component to regulate the article, as appro-  
14    priate.

15            “(b) *STATEMENT.*—Not later than 60 days after the  
16    receipt of the request described in subsection (a), the Sec-  
17    retary shall determine the classification of the article or the  
18    component of the Food and Drug Administration that will  
19    regulate the article and shall provide to the person a written  
20    statement that identifies the classification of the article or  
21    the component of the Food and Drug Administration that  
22    will regulate the article and the reasons for such determina-  
23    tion. The Secretary may not modify such statement except  
24    with the written consent of the person or for public health  
25    reasons.

1       “(c) *INACTION OF SECRETARY.*—If the Secretary does  
 2 not provide the statement within the 60-day period de-  
 3 scribed in subsection (b), the recommendation made by the  
 4 person under subsection (a) shall be considered to be a final  
 5 determination by the Secretary of the classification of the  
 6 article or the component of the Food and Drug Administra-  
 7 tion that will regulate the article and may not be modified  
 8 by the Secretary except with the written consent of the per-  
 9 son or for public health reasons.”.

10 **SEC. 403. USE OF DATA RELATING TO PREMARKET AP-**  
 11 **PROVAL.**

12       (a) *IN GENERAL.*—Section 520(h)(4) (21 U.S.C.  
 13 360j(h)(4)) is amended to read as follows:

14       “(4)(A) Any information contained in an application  
 15 for premarket approval filed with the Secretary pursuant  
 16 to section 515(c) (including information from clinical and  
 17 preclinical tests or studies that demonstrate the safety and  
 18 effectiveness of a device, but excluding descriptions of meth-  
 19 ods of manufacture and product composition) shall be  
 20 available, 6 years after the application has been approved  
 21 by the Secretary, for use by the Secretary in—

22               “(i) approving another device;

23               “(ii) determining whether a product development  
 24 protocol has been completed, under section 515 for an-  
 25 other device;

1           “(iii) establishing a performance standard or  
2           special control under this Act; or

3           “(iv) classifying or reclassifying another device  
4           under section 513 and subsection (l)(2).

5           “(B) The publicly available detailed summaries of in-  
6           formation respecting the safety and effectiveness of devices  
7           required by paragraph (1)(A) shall be available for use by  
8           the Secretary as the evidentiary basis for the agency action  
9           described in subparagraph (A).”.

10          (b) *CONFORMING AMENDMENT.*—Section 517(a) (21  
11          U.S.C. 360g(a)) is amended—

12                 (1) in paragraph (8), by adding “or” at the end;

13                 (2) in paragraph (9), by striking “, or” and in-  
14                 serting a comma; and

15                 (3) by striking paragraph (10).

16          **SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR**  
17                         **PRODUCT REVIEW.**

18          (a) *PREMARKET APPROVAL.*—Section 515(d)(1)(A)  
19          (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end  
20          the following flush sentences:

21          “In making the determination whether to approve or deny  
22          the application, the Secretary shall rely on the conditions  
23          of use included in the proposed labeling as the basis for  
24          determining whether or not there is a reasonable assurance  
25          of safety and effectiveness, if the proposed labeling is neither

1 *false nor misleading. In determining whether or not such*  
 2 *labeling is false or misleading, the Secretary shall fairly*  
 3 *evaluate all material facts pertinent to the proposed label-*  
 4 *ing.”.*

5 (b) *PREMARKET NOTIFICATION.*—Section 513(i)(1)  
 6 (21 U.S.C. 360c(i)(1)) is amended by adding at the end  
 7 the following:

8 “(C) Whenever the Secretary requests information to  
 9 demonstrate that the devices with differing technological  
 10 characteristics are substantially equivalent, the Secretary  
 11 shall only request information that is necessary to make  
 12 a substantial equivalence determination. In making such  
 13 a request, the Secretary shall consider the least burdensome  
 14 means of demonstrating substantial equivalence and shall  
 15 request information accordingly.

16 “(D) The determinations of the Secretary under this  
 17 section and section 513(f)(1) with respect to the intended  
 18 use of a device shall be based on the intended use included  
 19 in proposed labeling of the device submitted in a report  
 20 under section 510(k).”.

21 **SEC. 405. DEFINITION OF A DAY FOR PURPOSES OF PROD-**  
 22 **UCT REVIEW.**

23 Section 201 (21 U.S.C. 321) is amended by adding  
 24 at the end the following:

1       “(ii) *In any provision relating to a review of any ap-*  
 2 *plication or submission (including a petition, notification,*  
 3 *and any other similar form of request), made under this*  
 4 *Act with respect to an article that is a new drug, device,*  
 5 *biological product, new animal drug, an animal feed bear-*  
 6 *ing or containing a new animal drug, color additive, or*  
 7 *food additive, that is submitted to the Secretary to obtain*  
 8 *marketing approval, to obtain classification of a device*  
 9 *under section 513(f)(1), or to establish or clarify the regu-*  
 10 *latory status of the article—*

11               “(1) *the term ‘day’ means a calendar day in*  
 12 *which the Secretary has responsibility to review such*  
 13 *an application or submission; and*

14               “(2) *a reference to a date relating to the receipt*  
 15 *of such an application or submission by the Secretary*  
 16 *shall be deemed to be a reference to the date on which*  
 17 *the Secretary receives a complete application or sub-*  
 18 *mission within the meaning of this Act and the regu-*  
 19 *lations promulgated under this Act.”.*

20 **SEC. 406. CERTAINTY OF REVIEW TIMEFRAMES.**

21       (a) **CLARIFICATION ON THE 90-DAY TIMEFRAME FOR**  
 22 **PREMARKET NOTIFICATION REVIEWS.**—Section 510(k) (21  
 23 U.S.C. 360) is amended by adding at the end the following  
 24 *flush sentence:*

1 “The Secretary shall review the notification required by this  
 2 subsection and make a determination under section  
 3 513(f)(1) not later than 90 days after receiving the notifica-  
 4 tion.”.

5 (b) *CERTAINTY OF 180-DAY REVIEW TIMEFRAME.*—  
 6 Section 515(d) (21 U.S.C. 360e(d)), as amended by section  
 7 302, is amended by inserting after paragraph (2) the follow-  
 8 ing:

9 “(3) Except as provided in paragraph (1), the period  
 10 for the review of an application by the Secretary under this  
 11 subsection shall be not more than 180 days. Such period  
 12 may not be restarted or extended even if the application  
 13 is amended.”.

14 **SEC. 407. LIMITATIONS ON INITIAL CLASSIFICATION DE-**  
 15 **TERMINATIONS.**

16 Section 510 (21 U.S.C. 360) is amended by adding  
 17 at the end the following:

18 “(m) The Secretary may not withhold a determination  
 19 of the initial classification of a device under section  
 20 513(f)(1) because of a failure to comply with any provision  
 21 of this Act that is unrelated to a substantial equivalence  
 22 decision, including a failure to comply with the require-  
 23 ments relating to good manufacturing practices under sec-  
 24 tion 520(f).”.

1 **SEC. 408. CLARIFICATION WITH RESPECT TO A GENERAL**  
 2 **USE AND SPECIFIC USE OF A DEVICE.**

3 *Not later than 270 days after the date of enactment*  
 4 *of this section, the Secretary of Health and Human Services*  
 5 *shall promulgate a final regulation specifying the general*  
 6 *principles that the Secretary of Health and Human Serv-*  
 7 *ices will consider in determining when a specific intended*  
 8 *use of a device is not reasonably included within a general*  
 9 *use of such device for purposes of a determination of sub-*  
 10 *stantial equivalence under section 513(f)(1) of the Federal*  
 11 *Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).*

12 **SEC. 409. CLARIFICATION OF THE NUMBER OF REQUIRED**  
 13 **CLINICAL INVESTIGATIONS FOR APPROVAL.**

14 *(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21*  
 15 *U.S.C. 360c(a)(3)(A)) is amended by striking “clinical in-*  
 16 *vestigations” and inserting “1 or more clinical investiga-*  
 17 *tions”.*

18 *(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d))*  
 19 *is amended by adding at the end the following: “Substantial*  
 20 *evidence may, as appropriate, consist of data from 1 ade-*  
 21 *quate and well-controlled clinical investigation and con-*  
 22 *firmatory evidence (obtained prior to or after such inves-*  
 23 *tigation), if the Secretary determines, based on relevant*  
 24 *science, that such data and evidence are sufficient to estab-*  
 25 *lish effectiveness.”.*

1 **SEC. 410. PROHIBITED ACTS.**

2 *Section 301(l) (21 U.S.C. 331(l)) is repealed.*

3 **TITLE V—IMPROVING**  
 4 **ACCOUNTABILITY**

5 **SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND**  
 6 **ANNUAL REPORT.**

7 *Section 903(b) (21 U.S.C. 393(b)), as amended by sec-*  
 8 *tion 201, is further amended by adding at the end the fol-*  
 9 *lowing:*

10 “(4) AGENCY PLAN FOR STATUTORY COMPLI-

11 ANCE.—

12 “(A) IN GENERAL.—Not later than 180

13 days after the date of enactment of this para-

14 graph, the Secretary, after consultation with rel-

15 evant experts, health care professionals, rep-

16 resentatives of patient and consumer advocacy

17 groups, and the regulated industry, shall develop

18 and publish in the Federal Register a plan

19 bringing the Secretary into compliance with each

20 of the obligations of the Secretary under this Act

21 and other relevant statutes. The Secretary shall

22 biannually review the plan and shall revise the

23 plan as necessary, in consultation with such per-

24 sons.

25 “(B) OBJECTIVES OF AGENCY PLAN.—The

26 plan required by subparagraph (A) shall estab-



1        *lish objectives, and mechanisms to be used by the*  
2        *Secretary, acting through the Commissioner, in-*  
3        *cluding objectives and mechanisms that—*

4                *“(i) minimize deaths of, and harm to,*  
5                *persons who use or may use an article regu-*  
6                *lated under this Act;*

7                *“(ii) maximize the clarity of, and the*  
8                *availability of information about, the proc-*  
9                *ess for review of applications and submis-*  
10               *sions (including petitions, notifications,*  
11               *and any other similar forms of request)*  
12               *made under this Act, including information*  
13               *for potential consumers and patients con-*  
14               *cerning new products;*

15               *“(iii) implement all inspection and*  
16               *postmarket monitoring provisions of this*  
17               *Act by July 1, 1999;*

18               *“(iv) ensure access to the scientific and*  
19               *technical expertise necessary to ensure com-*  
20               *pliance by the Secretary with the statutory*  
21               *obligations described in subparagraph (A);*

22               *“(v) establish a schedule to bring the*  
23               *Administration into full compliance by*  
24               *July 1, 1999, with the time periods speci-*  
25               *fied in this Act for the review of all applica-*

tions and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

“(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

“(5) ANNUAL REPORT.—

“(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

“(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

“(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

“(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

“(iv) identifies any regulatory policy that has a significant impact on compliance

1           *with any objective of the plan or any statu-*  
2           *tory obligation; and*

3           “(v) sets forth any proposed revision to  
4           any such regulatory policy, or objective of  
5           the plan that has not been met.

6           “(B) *STATISTICAL INFORMATION.*—*The sta-*  
7           *tistical information described in subparagraph*  
8           *(A)(i) shall include a full statistical presentation*  
9           *relating to all applications and submissions (in-*  
10          *cluding petitions, notifications, and any other*  
11          *similar forms of request) made under this Act*  
12          *and approved or subject to final action by the*  
13          *Secretary during the year covered by the report.*  
14          *In preparing the statistical presentation, the*  
15          *Secretary shall take into account the date of—*

16               “(i) the submission of any investiga-  
17               tional application;

18               “(ii) the application of any clinical  
19               hold;

20               “(iii) the submission of any applica-  
21               tion or submission (including a petition,  
22               notification, and any other similar form of  
23               request) made under this Act for approval  
24               or clearance;

1                   “(iv) the acceptance for filing of any  
2                   application or submission described in  
3                   clause (iii) for approval or clearance;

4                   “(v) the occurrence of any  
5                   unapprovable action;

6                   “(vi) the occurrence of any approvable  
7                   action; and

8                   “(vii) the approval or clearance of any  
9                   application or submission described in  
10                  clause (iii).”.

11 ***TITLE VI—BETTER ALLOCATION***  
12 ***OF RESOURCES BY SETTING***  
13 ***PRIORITIES***

14 ***SEC. 601. MINOR MODIFICATIONS.***

15           (a) *ACTION ON INVESTIGATIONAL DEVICE EXEMP-*  
16 *TIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by*  
17 *adding at the end the following:*

18           “(6)(A) *The Secretary shall, not later than 120 days*  
19 *after the date of enactment of this paragraph, by regulation*  
20 *modify parts 812 and 813 of title 21, Code of Federal Regu-*  
21 *lations to update the procedures and conditions under*  
22 *which a device intended for human use may, upon applica-*  
23 *tion by the sponsor of the device, be granted an exemption*  
24 *from the requirements of this Act.*

1       “(B) The regulation shall permit developmental  
2 changes in a device (including manufacturing changes) in  
3 response to information collected during an investigation  
4 without requiring an additional approval of an application  
5 for an investigational device exemption or the approval of  
6 a supplement to such application, if the sponsor of the in-  
7 vestigation determines, based on credible information, prior  
8 to making any such changes, that the changes—

9               “(i) do not affect the scientific soundness of an  
10       investigational plan submitted under paragraph  
11       (3)(A) or the rights, safety, or welfare of the human  
12       subjects involved in the investigation; and

13               “(ii) do not constitute a significant change in  
14       design, or a significant change in basic principles of  
15       operation, of the device.”.

16       (b) ACTION ON APPLICATION.—Section 515(d)(1)(B)  
17 (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end  
18 the following:

19               “(iii) The Secretary shall accept and review data and  
20 any other information from investigations conducted under  
21 the authority of regulations required by section 520(g), to  
22 make a determination of whether there is a reasonable as-  
23 surance of safety and effectiveness of a device subject to a  
24 pending application under this section if—

1           “(I) the data or information is derived from in-  
2       vestigations of an earlier version of the device, the de-  
3       vice has been modified during or after the investiga-  
4       tions (but prior to submission of an application  
5       under subsection (c)) and such a modification of the  
6       device does not constitute a significant change in the  
7       design or in the basic principles of operation of the  
8       device that would invalidate the data or information;  
9       or

10           “(II) the data or information relates to a device  
11       approved under this section, is available for use under  
12       this Act, and is relevant to the design and intended  
13       use of the device for which the application is pend-  
14       ing.”.

15       (c) ACTION ON SUPPLEMENTS.—Section 515(d) (21  
16 U.S.C. 360e(d)), as amended by section 302, is further  
17 amended by adding at the end the following:

18       “(6)(A)(i) A supplemental application shall be re-  
19 quired for any change to a device subject to an approved  
20 application under this subsection that affects safety or effec-  
21 tiveness, unless such change is a modification in a manu-  
22 facturing procedure or method of manufacturing and the  
23 holder of the approved application submits a written notice  
24 to the Secretary that describes in detail the change, summa-  
25 rizes the data or information supporting the change, and

1 *informs the Secretary that the change has been made under*  
2 *the requirements of section 520(f).*

3       “(ii) *The holder of an approved application who sub-*  
4 *mits a notice under clause (i) with respect to a manufactur-*  
5 *ing change of a device shall not distribute the device for*  
6 *a period of 14 days after the date on which the Secretary*  
7 *receives the notice.*

8       “(B)(i) *Subject to clause (ii), in reviewing a supple-*  
9 *ment to an approved application, for an incremental*  
10 *change to the design of a device that affects safety or effec-*  
11 *tiveness, the Secretary shall approve such supplement if—*

12               “(I) *nonclinical data demonstrate that the design*  
13 *modification creates the intended additional capacity,*  
14 *function, or performance of the device; and*

15               “(II) *clinical data from the approved applica-*  
16 *tion and any supplement to the approved application*  
17 *provide a reasonable assurance of safety and effective-*  
18 *ness for the changed device.*

19       “(ii) *The Secretary may require, when necessary, ad-*  
20 *ditional clinical data to evaluate the design modification*  
21 *to provide a reasonable assurance of safety and effective-*  
22 *ness.”.*

1 **SEC. 602. ENVIRONMENTAL IMPACT REVIEW.**

2 *Chapter VII (21 U.S.C. 371 et seq.), as amended by*  
 3 *section 402, is further amended by adding at the end the*  
 4 *following:*

5 **“SEC. 742. ENVIRONMENTAL IMPACT REVIEW.**

6 *“Notwithstanding any other provision of law, no ac-*  
 7 *tion by the Secretary pursuant to this Act shall be subject*  
 8 *to an environmental assessment, an environmental impact*  
 9 *statement, or other environmental consideration unless the*  
 10 *Secretary demonstrates, in writing—*

11 *“(1) that there is a reasonable probability that*  
 12 *the environmental impact of the action is sufficiently*  
 13 *substantial and within the factors that the Secretary*  
 14 *is authorized to consider under this Act; and*

15 *“(2) that consideration of the environmental im-*  
 16  *pact will directly affect the decision on the action.”.*

17 **SEC. 603. EXEMPTION OF CERTAIN CLASSES OF DEVICES**  
 18 **FROM PREMARKET NOTIFICATION REQUIRE-**  
 19 **MENT.**

20 *(a) CLASS I AND CLASS II DEVICES.—Section 510(k)*  
 21 *(21 U.S.C. 360(k)) is amended by striking “intended for*  
 22 *human use” and inserting “intended for human use (except*  
 23 *a device that is classified into class I under section 513*  
 24 *or 520 unless the Secretary determines such device is in-*  
 25 *tended for a use that is of substantial importance in pre-*  
 26 *venting impairment of human health or such device pre-*



1 *sents a potential unreasonable risk of illness or injury, or*  
 2 *a device that is classified into class II under section 513*  
 3 *or 520 and is exempt from the requirements of this sub-*  
 4 *section under subsection (l))”.*

5 (b) *PUBLICATION OF EXEMPTION.*—Section 510 (21  
 6 U.S.C. 360) is amended by inserting after subsection (k)  
 7 the following:

8 “(l)(1) Not later than 30 days after the date of enact-  
 9 ment of this subsection, the Secretary shall publish in the  
 10 Federal Register a list of each type of class II device that  
 11 does not require a notification under subsection (k) to pro-  
 12 vide reasonable assurance of safety and effectiveness. Each  
 13 type of class II device identified by the Secretary not to  
 14 require the notification shall be exempt from the require-  
 15 ment to provide notification under subsection (k) as of the  
 16 date of the publication of the list in the Federal Register.

17 “(2) Beginning on the date that is 1 day after the date  
 18 of the publication of a list under this subsection, the Sec-  
 19 retary may exempt a class II device from the notification  
 20 requirement of subsection (k), upon the Secretary’s own ini-  
 21 tiative or a petition of an interested person, if the Secretary  
 22 determines that such notification is not necessary to assure  
 23 the safety and effectiveness of the device. The Secretary shall  
 24 publish in the Federal Register notice of the intent of the  
 25 Secretary to exempt the device, or of the petition, and pro-

1 *vide a 30-day comment period for public comment. Within*  
 2 *120 days after the issuance of the notice in the Federal Reg-*  
 3 *ister, the Secretary shall publish an order in the Federal*  
 4 *Register that sets forth the final determination of the Sec-*  
 5 *retary regarding the exemption of the device that was the*  
 6 *subject of the notice.”.*

7 **SEC. 604. EVALUATION OF AUTOMATIC CLASS III DESIGNA-**  
 8 **TION.**

9 *Section 513(f) (21 U.S.C. 360c(f)) is amended—*

10 *(1) in paragraph (1)—*

11 *(A) in subparagraph (B), by striking*  
 12 *“paragraph (2)” and inserting “paragraph (3)”;*  
 13 *and*

14 *(B) in the last sentence, by striking “para-*  
 15 *graph (2)” and inserting “paragraph (2) or*  
 16 *(3)”;*

17 *(2) by redesignating paragraphs (2) and (3) as*  
 18 *paragraphs (3) and (4), respectively; and*

19 *(3) by inserting after paragraph (1) the follow-*  
 20 *ing:*

21 *“(2)(A) Any person who submits a report under sec-*  
 22 *tion 510(k) for a type of device that has not been previously*  
 23 *classified under this Act, and that is classified into class*  
 24 *III under paragraph (1), may request, within 30 days after*  
 25 *receiving written notice of such a classification, the Sec-*

1   retary to classify the device into class I or II under the  
2   criteria set forth in subparagraphs (A) through (C) sub-  
3   section (a)(1). The person may, in the request, recommend  
4   to the Secretary a classification for the device. The request  
5   shall describe the device and provide detailed information  
6   and reasons for the recommended classification.

7       “(B)(i) Not later than 60 days after the date of the  
8   submission of the request under subparagraph (A) for clas-  
9   sification of a device under the criteria set forth in subpara-  
10   graphs (A) through (C) of subsection (a)(1), the Secretary  
11   shall by written order classify the device. Such classification  
12   shall be the initial classification of the device for purposes  
13   of paragraph (1) and any device classified under this para-  
14   graph into class I or II shall be a predicate device for deter-  
15   mining substantial equivalence under paragraph (1).

16       “(ii) A device that remains in class III under this sub-  
17   paragraph shall be deemed to be adulterated within the  
18   meaning of section 501(f)(1)(B) until approved under sec-  
19   tion 515 or exempted from such approval under section  
20   520(g).

21       “(C) Within 30 days after the issuance of an order  
22   classifying a device under this paragraph, the Secretary  
23   shall publish a notice in the Federal Register announcing  
24   such classification.”.

1 **SEC. 605. SECRETARY'S DISCRETION TO TRACK DEVICES.**

2       (a) *RELEASE OF INFORMATION.*—Section 519(e) (21  
3 *U.S.C. 360i(e)) is amended by adding at the end the follow-*  
4 *ing flush sentence:*

5 *“Any patient receiving a device subject to tracking under*  
6 *this section may refuse to release, or refuse permission to*  
7 *release, the patient’s name, address, social security number,*  
8 *or other identifying information for the purpose of track-*  
9 *ing.”.*

10       (b) *PUBLICATION OF CERTAIN DEVICES.*—Not later  
11 *than 180 days after the date of enactment of this Act, the*  
12 *Secretary of Health and Human Services shall develop and*  
13 *publish in the Federal Register a list that identifies each*  
14 *type of device subject to tracking under section 519(e)(1)*  
15 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
16 *360i(e)(1)). Each device not identified by the Secretary of*  
17 *Health and Human Services under this subsection or des-*  
18 *ignated by the Secretary under section 519(e)(2) shall be*  
19 *deemed to be exempt from the mandatory tracking require-*  
20 *ment under section 519 of such Act. The Secretary of Health*  
21 *and Human Services shall have authority to modify the list*  
22 *of devices exempted from the mandatory tracking require-*  
23 *ments.*

1 **SEC. 606. SECRETARY'S DISCRETION TO CONDUCT**  
 2 **POSTMARKET SURVEILLANCE.**

3 (a) *IN GENERAL.*—Section 522 (21 U.S.C. 360l) is  
 4 amended by striking “SEC. 522.” and all that follows  
 5 through “(2) DISCRETIONARY SURVEILLANCE.—The” and  
 6 inserting the following:

7 “SEC. 522. (a) *DISCRETIONARY SURVEILLANCE.*—  
 8 *The*”.

9 (b) *SURVEILLANCE APPROVAL.*—Section 522(b) (21  
 10 U.S.C. 360l(b)) is amended to read as follows:

11 “(b) *SURVEILLANCE APPROVAL.*—

12 “(1) *IN GENERAL.*—Each manufacturer that re-  
 13 ceives notice from the Secretary that the manufac-  
 14 turer is required to conduct surveillance of a device  
 15 under subsection (a) shall, not later than 30 days  
 16 after receiving the notice, submit for the approval of  
 17 the Secretary, a plan for the required surveillance.

18 “(2) *DETERMINATION.*—Not later than 60 days  
 19 after the receipt of the plan, the Secretary shall deter-  
 20 mine if a person proposed in the plan to conduct the  
 21 surveillance has sufficient qualifications and experi-  
 22 ence to conduct the surveillance and if the plan will  
 23 result in the collection of useful data that can reveal  
 24 unforeseen adverse events or other information nec-  
 25 essary to protect the public health and to provide safe-  
 26 ty and effectiveness information for the device.

1           “(3) *LIMITATION ON PLAN APPROVAL.*—*The Sec-*  
 2           *retary may not approve the plan until the plan has*  
 3           *been reviewed by a qualified scientific and technical*  
 4           *review committee established by the Secretary.”.*

5           *(c) DURATION OF SURVEILLANCE.*—*Section 522 (21*  
 6           *U.S.C. 360l), as amended by subsection (b), is further*  
 7           *amended by adding at the end the following:*

8           “(c) *DURATION OF SURVEILLANCE.*—

9           “(1) *IN GENERAL.*—*Each manufacturer required*  
 10          *to conduct surveillance of a device under subsection*  
 11          *(a) shall be required to conduct such surveillance for*  
 12          *not longer than 24 months.*

13          “(2) *EXTENSION OF THE PERIOD OF SURVEIL-*  
 14          *LANCE.*—*If the Secretary determines that additional*  
 15          *surveillance is needed to identify the incidence of ad-*  
 16          *verse events documented during the initial period of*  
 17          *surveillance that were not foreseen at the time of ap-*  
 18          *proval or classification of the device, the Secretary*  
 19          *may extend the period of surveillance for such time*  
 20          *as may be necessary after providing the person re-*  
 21          *quired to conduct such surveillance an opportunity*  
 22          *for an informal hearing to determine whether or not*  
 23          *additional surveillance is appropriate and to deter-*  
 24          *mine the appropriate period, if any, for such surveil-*  
 25          *lance.”.*

1 **SEC. 607. REPORTING.**

2 (a) *REPORTS.*—Section 519 (21 U.S.C. 360i) is  
3 amended—

4 (1) in subsection (a)—

5 (A) in the first sentence by striking “make  
6 such reports, and provide such information,”  
7 and inserting “and submit such samples and  
8 components of devices (as required by paragraph  
9 (10)),”; and

10 (B) by inserting after the first sentence the  
11 following: “Every person who is a manufacturer  
12 or importer of a device intended for human use  
13 shall make reports, and provide such informa-  
14 tion, as the Secretary may by regulation reason-  
15 ably require to assure that such device is not  
16 adulterated or misbranded and to assure the  
17 safety and effectiveness of such device.”;

18 (C) in the last sentence by striking “sen-  
19 tence” and inserting “sentences”;

20 (D) in paragraph (8), by striking “; and”  
21 and inserting a semicolon; and

22 (E) by striking paragraph (9) and inserting  
23 the following:

24 “(9) shall require distributors to keep records  
25 and make such records available to the Secretary  
26 upon request; and”;

1           (2) *by striking subsection (d); and*

2           (3) *in subsection (f), by striking “, importer, or*  
 3           *distributor” each place it appears and inserting “or*  
 4           *importer”.*

5           (b) *REGISTRATION.—Section 510(g) (21 U.S.C.*  
 6           *360(g)) is amended—*

7           (1) *by redesignating paragraph (4) as para-*  
 8           *graph (5);*

9           (2) *by inserting after paragraph (3), the follow-*  
 10          *ing:*

11           “(4) *any distributor who acts as a wholesale dis-*  
 12          *tributor of devices, and who does not manufacture, re-*  
 13          *package, process, or relabel a device; or”;* and

14           (3) *by adding at the end the following flush sen-*  
 15          *tence:*

16          *“In this subsection, the term ‘wholesale distributor’ means*  
 17          *any person who distributes a device from the original place*  
 18          *of manufacture to the person who makes the final delivery*  
 19          *or sale of the device to the ultimate consumer or user.”.*

20       **SEC. 608. PILOT AND SMALL-SCALE MANUFACTURE.**

21          *Section 505(c) (21 U.S.C. 355(c)) is amended by add-*  
 22          *ing at the end the following:*

23          “(4) *A new drug manufactured in a pilot or other*  
 24          *small facility may be used to demonstrate the safety and*  
 25          *effectiveness of the new drug and to obtain approval of the*



1 *new drug prior to scaling up to a larger facility, unless*  
2 *the Secretary determines that a full scale production facil-*  
3 *ity is necessary to ensure the safety or effectiveness of the*  
4 *new drug.”.*

5 **SEC. 609. REQUIREMENTS FOR RADIOPHARMACEUTICALS.**

6 (a) *REQUIREMENTS.—*

7 (1) *REGULATIONS.—*

8 (A) *PROPOSED REGULATIONS.—Not later*  
9 *than 180 days after the date of enactment of this*  
10 *Act, the Secretary of Health and Human Serv-*  
11 *ices, after consultation with patient advocacy*  
12 *groups, associations, physicians licensed to use*  
13 *radiopharmaceuticals, and the regulated indus-*  
14 *try, shall issue proposed regulations governing*  
15 *the approval of radiopharmaceuticals designed*  
16 *for diagnosis and monitoring of diseases and*  
17 *conditions. The regulations shall provide that the*  
18 *determination of the safety and effectiveness of*  
19 *such a radiopharmaceutical under section 505 of*  
20 *the Federal Food, Drug, and Cosmetic Act (21*  
21 *U.S.C. 355) or section 351 of the Public Health*  
22 *Service Act (42 U.S.C. 262) shall include (but*  
23 *not be limited to) consideration of the proposed*  
24 *use of the radiopharmaceutical in the practice of*  
25 *medicine, the pharmacological and toxicological*

1        *activity of the radiopharmaceutical (including*  
 2        *any carrier or ligand component of the*  
 3        *radiopharmaceutical), and the estimated ab-*  
 4        *sorbed radiation dose of the*  
 5        *radiopharmaceutical.*

6                (B) *FINAL REGULATIONS.*—*Not later than*  
 7        *18 months after the date of enactment of this*  
 8        *Act, the Secretary shall promulgate final regula-*  
 9        *tions governing the approval of the*  
 10        *radiopharmaceuticals.*

11              (2) *SPECIAL RULE.*—*In the case of a*  
 12        *radiopharmaceutical intended to be used for diag-*  
 13        *nostic or monitoring purposes, the indications for*  
 14        *which such radiopharmaceutical is approved for mar-*  
 15        *keting may, in appropriate cases, refer to manifesta-*  
 16        *tions of disease (such as biochemical, physiological,*  
 17        *anatomic, or pathological processes) common to, or*  
 18        *present in, 1 or more disease states.*

19              (b) *DEFINITION.*—*In this section, the term*  
 20        *“radiopharmaceutical” means—*

21              (1) *an article—*

22                      (A) *that is intended for use in the diagnosis*  
 23        *or monitoring of a disease or a manifestation of*  
 24        *a disease in humans; and*

1                   *(B) that exhibits spontaneous disintegration*  
 2                   *of unstable nuclei with the emission of nuclear*  
 3                   *particles or photons; or*

4                   *(2) any nonradioactive reagent kit or nuclide*  
 5                   *generator that is intended to be used in the prepara-*  
 6                   *tion of any such article.*

7   **SEC. 610. MODERNIZATION OF REGULATION OF BIOLOGI-**  
 8                   **CAL PRODUCTS.**

9                   *(a) LICENSES.—*

10                   *(1) IN GENERAL.—Section 351(a) of the Public*  
 11                   *Health Service (42 U.S.C. 262(a)) is amended to read*  
 12                   *as follows:*

13                   *“(a)(1) Except as provided in paragraph (4), no per-*  
 14                   *son shall introduce or deliver for introduction into inter-*  
 15                   *state commerce any biological product unless—*

16                   *“(A) a biologics license is in effect for the biologi-*  
 17                   *cal product; and*

18                   *“(B) each package of the biological product is*  
 19                   *plainly marked with—*

20                   *“(i) the proper name of the biological prod-*  
 21                   *uct contained in the package;*

22                   *“(ii) the name, address, and applicable li-*  
 23                   *cense number of the manufacturer of the biologi-*  
 24                   *cal product; and*

1                   “(iii) the expiration date of the biological  
2                   product.

3           “(2)(A) The Secretary shall establish, by regulation,  
4 requirements for the approval, suspension, and revocation  
5 of biologics licenses.

6           “(B) The Secretary shall approve a biologics license  
7 application on the basis of a demonstration that—

8                   “(i) the biological product that is the subject of  
9 the application is safe, pure, and potent; and

10                  “(ii) the facility in which the biological product  
11 is manufactured, processed, packed, or held meets  
12 standards designed to assure that the biological prod-  
13 uct continues to be safe, pure, and potent.

14           “(3) A biologics license application shall be approved  
15 only if the applicant (or other appropriate person) consents  
16 to the inspection of the facility that is the subject of the  
17 application, in accordance with subsection (c).

18           “(4) The Secretary shall prescribe requirements under  
19 which a biological product undergoing investigation shall  
20 be exempt from the requirements of paragraph (1).”.

21                   (2) *ELIMINATION OF EXISTING LICENSE RE-*  
22 *QUIREMENT.*—Section 351(d) of the Public Health  
23 Service Act (42 U.S.C. 262(d)) is amended—

24                           (A) by striking “(d)(1)” and all that follows  
25 through “of this section.”;

1                   (B) in paragraph (2)—

2                   (i) by striking “(2)(A) Upon” and in-  
3                   serting “(d)(1) Upon;” and

4                   (ii) by redesignating subparagraph (B)  
5                   as paragraph (2); and

6                   (C) in paragraph (2) (as so redesignated by  
7                   subparagraph (B)(ii))—

8                   (i) by striking “subparagraph (A)”  
9                   and inserting “paragraph (1)”; and

10                  (ii) by striking “this subparagraph”  
11                  each place it appears and inserting “this  
12                  paragraph”.

13           (b) *LABELING*.—Section 351(b) of the Public Health  
14   Service Act (42 U.S.C. 262(b)) is amended to read as fol-  
15   lows:

16           “(b) No person shall falsely label or mark any package  
17   or container of any biological product or alter any label  
18   or mark on the package or container of the biological prod-  
19   uct so as to falsify the label or mark.”.

20           (c) *INSPECTION*.—Section 351(c) of the Public Health  
21   Service Act (42 U.S.C. 262(c)) is amended by striking  
22   “virus, serum,” and all that follows and inserting “biologi-  
23   cal product.”.

1       (d) *DEFINITION; APPLICATION.*—Section 351 of the  
 2   *Public Health Service Act (42 U.S.C. 262) is amended by*  
 3   *adding at the end the following:*

4       “(i) *In this section, the term ‘biological product’ means*  
 5   *a virus, therapeutic serum, toxin, antitoxin, vaccine, blood,*  
 6   *blood component or derivative, allergenic product, analo-*  
 7   *gous product, or arsphenamine or derivative of arsphen-*  
 8   *amine (or any other trivalent organic arsenic compound),*  
 9   *applicable to the prevention, treatment, or cure of a disease*  
 10   *or condition of human beings.”.*

11       (e) *CONFORMING AMENDMENT.*—Section 503(g)(4) (21  
 12   *U.S.C. 353(g)(4)) is amended—*

13               (1) *in subparagraph (A)—*

14                       (A) *by striking “section 351(a)” and insert-*  
 15                       *ing “section 351(i)”;* and

16                       (B) *by striking “262(a)” and inserting*  
 17                       *“262(i)”;* and

18               (2) *in subparagraph (B)(iii), by striking “prod-*  
 19   *uct or establishment license under subsection (a) or*  
 20   *(d)” and inserting “biologics license application*  
 21   *under subsection (a)”.*

22       (f) *SPECIAL RULE.*—*The Secretary of Health and*  
 23   *Human Services shall take measures to minimize dif-*  
 24   *ferences in the review and approval of products required*  
 25   *to have approved biologics license applications under sec-*

tion 351 of the Public Health Service Act (42 U.S.C. 262)  
 and products required to have approved full new drug ap-  
 plications under section 505(b)(1) of the Federal Food,  
 Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

**SEC. 611. APPROVAL OF SUPPLEMENTAL APPLICATIONS  
 FOR APPROVED PRODUCTS.**

(a) *PERFORMANCE STANDARDS.*—Not later than 180  
 days after the date of enactment of this section, the Sec-  
 retary of Health and Human Services shall publish in the  
 Federal Register performance standards for the prompt re-  
 view of supplemental applications submitted for approved  
 articles under the Federal Food, Drug, and Cosmetic Act  
 (21 U.S.C. 321 et seq.).

(b) *GUIDANCE TO INDUSTRY.*—Not later than 180 days  
 after the date of enactment of this section, the Secretary  
 of Health and Human Services shall issue final guidances  
 to clarify the requirements for, and facilitate the submission  
 of data to support, the approval of supplemental applica-  
 tions for the approved articles described in subsection (a).  
 The guidances shall—

(1) *clarify circumstances in which published  
 matter may be the basis for approval of a supple-  
 mental application;*

(2) *specify data requirements that will avoid du-  
 plication of previously submitted data by recognizing*

1        *the availability of data previously submitted in sup-*  
2        *port of an original application; and*

3            *(3) define supplemental applications that are eli-*  
4        *gible for priority review.*

5        *(c) RESPONSIBILITIES OF CENTERS.—The Secretary of*  
6        *Health and Human Services shall designate an individual*  
7        *in each center within the Food and Drug Administration*  
8        *(except the Center for Food Safety and Applied Nutrition)*  
9        *to be responsible for—*

10            *(1) encouraging the prompt review of supple-*  
11        *mental applications for approved articles; and*

12            *(2) working with sponsors to facilitate the devel-*  
13        *opment and submission of data to support supple-*  
14        *mental applications.*

15        *(d) COLLABORATION.—The Secretary of Health and*  
16        *Human Services shall implement programs and policies*  
17        *that will foster collaboration between the Food and Drug*  
18        *Administration, the National Institutes of Health, profes-*  
19        *sional medical and scientific societies, and other persons,*  
20        *to identify published and unpublished studies that may*  
21        *support a supplemental application, and to encourage*  
22        *sponsors to make supplemental applications or conduct fur-*  
23        *ther research in support of a supplemental application*  
24        *based, in whole or in part, on such studies.*



1 **SEC. 612. HEALTH CARE ECONOMIC INFORMATION.**

2       Section 502 (21 U.S.C. 352) is amended by adding  
3 at the end the following:

4       “(u) In the case of a health care economic statement  
5 that is included in labeling or advertising provided to a  
6 formulary committee, managed care organization, or simi-  
7 lar entity with responsibility for drug selection decisions  
8 (other than the label or approved physician package insert)  
9 relating to an indication approved under section 505 or 351  
10 of the Public Health Service Act (42 U.S.C. 262), if the  
11 health care economic statement is not based on competent  
12 and reliable scientific evidence. The only requirements ap-  
13 plicable to any such statement under this Act shall be the  
14 requirements of this paragraph. In this paragraph, the term  
15 ‘health care economic statement’ means any statement that  
16 identifies, measures, or compares the costs (direct, indirect,  
17 and intangible) and health care consequences of a drug to  
18 another drug, to another health care intervention for the  
19 same indication, or to no intervention, where the primary  
20 endpoint is an economic outcome.”.

21 **SEC. 613. EXPEDITING STUDY AND APPROVAL OF FAST**  
22 **TRACK DRUGS.**

23       (a) *IN GENERAL.*—Chapter V (21 U.S.C. 351 et seq.),  
24 as amended by section 102, is further amended by adding  
25 at the end the following:

1                   “SUBCHAPTER E—FAST TRACK DRUGS

2   **“SEC. 561. FAST TRACK DRUGS.**

3           “(a) *DESIGNATION OF DRUG AS A FAST TRACK*  
4 *DRUG.*—

5                   “(1) *IN GENERAL.*—*The Secretary shall facilitate*  
6 *development, and expedite review and approval of*  
7 *new drugs and biological products that are intended*  
8 *for the treatment of serious or life-threatening condi-*  
9 *tions and that demonstrate the potential to address*  
10 *unmet medical needs for such conditions. In this Act,*  
11 *such products shall be known as ‘fast track drugs’.*

12                   “(2) *REQUEST FOR DESIGNATION.*—*The sponsor*  
13 *of a drug (including a biological product) may re-*  
14 *quest the Secretary to designate the drug as a fast*  
15 *track drug. A request for the designation may be*  
16 *made concurrently with, or at any time after, submis-*  
17 *sion of an application for the investigation of the*  
18 *drug under section 505(i) or section 351(a)(4) of the*  
19 *Public Health Service Act.*

20                   “(3) *DESIGNATION.*—*Within 30 calendar days*  
21 *after the receipt of a request under paragraph (2), the*  
22 *Secretary shall determine whether the drug that is the*  
23 *subject of the request meets the criteria described in*  
24 *paragraph (1). If the Secretary finds that the drug*  
25 *meets the criteria, the Secretary shall designate the*

1       *drug as a fast track drug and shall take such actions*  
2       *as are appropriate to expedite the development and*  
3       *review of the drug.*

4       “(b) *APPROVAL OF APPLICATION FOR A FAST TRACK*  
5       *DRUG.—*

6               “(1) *IN GENERAL.—The Secretary may approve*  
7       *an application for approval of a fast track drug*  
8       *under section 505(b) or section 351 of the Public*  
9       *Health Service Act (21 U.S.C. 262) upon a deter-*  
10       *mination that the drug has an effect on a surrogate*  
11       *endpoint that is reasonably likely to predict clinical*  
12       *benefit.*

13              “(2) *LIMITATION.—Approval of a fast track drug*  
14       *under this subsection may be subject to the require-*  
15       *ments—*

16                   “(A) *that the sponsor conduct appropriate*  
17       *post-approval studies to validate the surrogate*  
18       *endpoint or otherwise confirm the clinical benefit*  
19       *of the drug; and*

20                   “(B) *that the sponsor submit copies of all*  
21       *promotional materials related to the fast track*  
22       *drug during the preapproval review period and*  
23       *following approval, at least 30 days prior to dis-*  
24       *semination of the materials for such period of*  
25       *time as the Secretary deems appropriate.*

1           “(3) *EXPEDITED WITHDRAWAL OF APPROVAL.*—

2           *The Secretary may withdraw approval of a fast track*  
 3           *drug using expedited procedures (as prescribed by the*  
 4           *Secretary in regulations) including a procedure that*  
 5           *provides an opportunity for an informal hearing, if—*

6                     “(A) *the sponsor fails to conduct any re-*  
 7                     *quired post-approval study of the fast track drug*  
 8                     *with due diligence;*

9                     “(B) *a post-approval study of the fast track*  
 10                    *drug fails to verify clinical benefit of the fast*  
 11                    *track drug;*

12                    “(C) *other evidence demonstrates that the*  
 13                    *fast track drug is not safe or effective under con-*  
 14                    *ditions of use of the drug; or*

15                    “(D) *the sponsor disseminates false or mis-*  
 16                    *leading promotional materials with respect to*  
 17                    *the fast track drug.*

18           “(c) *REVIEW OF INCOMPLETE APPLICATIONS FOR AP-*  
 19           *PROVAL OF A FAST TRACK DRUG.*—

20                    “(1) *IN GENERAL.*—*If preliminary evaluation by*  
 21                    *the Secretary of clinical efficacy data for a fast track*  
 22                    *drug under investigation shows evidence of effective-*  
 23                    *ness, the Secretary shall evaluate for filing, and may*  
 24                    *commence review of portions, of an application for*  
 25                    *the approval of the drug if the applicant provides a*

1     *schedule for submission of information necessary to*  
2     *make the application complete and any fee that may*  
3     *be required under section 736.*

4             “(2) *EXCEPTION.—Any time period for review of*  
5     *human drug applications that has been agreed to by*  
6     *the Secretary and that has been set forth in goals*  
7     *identified in letters of the Secretary (relating to the*  
8     *use of fees collected under section 736 to expedite the*  
9     *drug development process and the review of human*  
10    *drug applications) shall not apply to an application*  
11    *submitted under paragraph (1) until the date on*  
12    *which the application is complete.*

13            “(d) *AWARENESS EFFORTS.—The Secretary shall—*

14               “(1) *develop and widely disseminate to physi-*  
15    *cians, patient organizations, pharmaceutical and bio-*  
16    *technology companies, and other appropriate persons*  
17    *a comprehensive description of the provisions applica-*  
18    *ble to fast track drugs established under this section;*  
19    *and*

20               “(2) *establish an ongoing program to encourage*  
21    *the development of surrogate endpoints that are rea-*  
22    *sonably likely to predict clinical benefit for serious or*  
23    *life-threatening conditions for which there exist sig-*  
24    *nificant unmet medical needs.”.*

1       (b) *GUIDANCE*.—Within 1 year after the date of enact-  
 2   ment of this Act, the Secretary of Health and Human Serv-  
 3   ices shall issue guidance for fast track drugs that describes  
 4   the policies and procedures that pertain to section 561 of  
 5   the Federal Food, Drug, and Cosmetic Act.

6   **SEC. 614. MANUFACTURING CHANGES FOR DRUGS AND BIO-**  
 7                           **LOGICS.**

8       (a) *IN GENERAL*.—Chapter VII (21 U.S.C. 371 et  
 9   seq.), as amended by section 602, is further amended by  
 10 adding at the end the following:

11       “SUBCHAPTER E—MANUFACTURING CHANGES

12   **“SEC. 751. MANUFACTURING CHANGES.**

13       “(a) *IN GENERAL*.—A change in the manufacture of  
 14 a new drug, including a biological product, may be made  
 15 in accordance with this section.

16       “(b) *CHANGES*.—

17       “(1) *VALIDATION*.—Before distributing a drug  
 18 made after a change in the manufacture of the drug  
 19 from the manufacturing process established in the ap-  
 20 proved new drug application under section 505, or li-  
 21 cense application under section 351 of the Public  
 22 Health Service Act, the applicant shall validate the  
 23 effect of the change on the identity, strength, quality,  
 24 purity, and potency of the drug as the identity,

1 *strength, quality, purity, and potency may relate to*  
 2 *the safety or effectiveness of the drug.*

3 “(2) *REPORTS.*—*The applicant shall report the*  
 4 *change described in paragraph (1) to the Secretary*  
 5 *and may distribute a drug made after the change as*  
 6 *follows:*

7 “(A) *MAJOR MANUFACTURING CHANGES.*

8 “(i) *IN GENERAL.*—*Major manufactur-*  
 9 *ing changes, which are of a type determined*  
 10 *by the Secretary to have substantial poten-*  
 11 *tial to adversely affect the identity, strength,*  
 12 *quality, purity, or potency of the drug as*  
 13 *the identity, strength, quality, purity, and*  
 14 *potency may relate to the safety or effective-*  
 15 *ness of a drug, shall be submitted to the*  
 16 *Secretary in a supplemental application*  
 17 *and drugs made after such changes may not*  
 18 *be distributed until the Secretary approves*  
 19 *the supplemental application.*

20 “(ii) *DEFINITION.*—*In this subpara-*  
 21 *graph, the term ‘major manufacturing*  
 22 *changes’ means—*

23 “(I) *changes in the qualitative or*  
 24 *quantitative formulation of a drug or*  
 25 *the specifications in the approved mar-*

1            *keting application for the drug (unless*  
2            *exempted by the Secretary from the re-*  
3            *quirements of this subparagraph);*

4            *“(II) changes that the Secretary*  
5            *determines by regulation or issuance of*  
6            *guidance require completion of an ap-*  
7            *propriate human study demonstrating*  
8            *equivalence of the drug to the drug*  
9            *manufactured before such changes; and*

10           *“(III) other changes that the Sec-*  
11           *retary determines by regulation or is-*  
12           *suance of guidance have a substantial*  
13           *potential to adversely affect the safety*  
14           *or effectiveness of the drug.*

15           *“(B) OTHER MANUFACTURING CHANGES.—*

16           *“(i) IN GENERAL.—As determined by*  
17           *the Secretary, manufacturing changes other*  
18           *than major manufacturing changes shall—*

19           *“(I) be made at any time and re-*  
20           *ported annually to the Secretary, with*  
21           *supporting data; or*

22           *“(II) be reported to the Secretary*  
23           *in a supplemental application.*



1                   “(ii) *DISTRIBUTION OF THE DRUG.*—

2                   *In the case of changes reported in accord-*  
 3                   *ance with clause (i)(II)—*

4                   “(I) *the applicant may distribute*  
 5                   *the drug 30 days after the Secretary*  
 6                   *receives the supplemental application*  
 7                   *unless the Secretary notifies the appli-*  
 8                   *cant within such 30-day period that*  
 9                   *prior approval of such supplemental*  
 10                   *application is required; and*

11                   “(II) *the Secretary shall, after*  
 12                   *making the notification to the appli-*  
 13                   *cant under subclause (I), approve or*  
 14                   *disapprove each such supplemental ap-*  
 15                   *plication.*

16                   “(iii) *SPECIAL RULE.*—*The Secretary*  
 17                   *may determine types of manufacturing*  
 18                   *changes after which distribution of a drug*  
 19                   *may commence at the time of submission of*  
 20                   *such supplemental application.”.*

21                   (b) *EXISTING LAW.*—*The requirements of the Federal*  
 22                   *Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and*  
 23                   *the Public Health Service Act (42 U.S.C. 201 et seq.) that*  
 24                   *are in effect on the date of enactment of this Act with respect*  
 25                   *to manufacturing changes shall remain in effect—*

1           (1) *for a period of 24 months after the date of*  
 2           *enactment of this Act; or*

3           (2) *until the effective date of regulations promul-*  
 4           *gated by the Secretary of Health and Human Services*  
 5           *implementing section 751 of the Federal Food, Drug,*  
 6           *and Cosmetic Act,*  
 7           *whichever is sooner.*

8       **SEC. 615. DATA REQUIREMENTS FOR DRUGS AND BIO-**  
 9                               **LOGICS.**

10       *Within 12 months after the date of enactment of this*  
 11       *Act, the Secretary of the Health and Human Services, act-*  
 12       *ing through the Commissioner of Food and Drugs, shall*  
 13       *issue guidance that describes when abbreviated study re-*  
 14       *ports may be submitted, in lieu of full reports, with a new*  
 15       *drug application under section 505 of the Federal Food,*  
 16       *Drug, and Cosmetic Act (21 U.S.C. 355) and with a bio-*  
 17       *logics license application under section 351 of the Public*  
 18       *Health Service Act (42 U.S.C. 262) for certain types of*  
 19       *studies. Such guidance shall describe the kinds of studies*  
 20       *for which abbreviated reports are appropriate and the ap-*  
 21       *propriate abbreviated report formats.*

22       **SEC. 616. FOOD CONTACT SUBSTANCES.**

23       (a) *FOOD CONTACT SUBSTANCES.*—*Section 409(a) (21*  
 24       *U.S.C. 348(a)) is amended—*

25               (1) *in paragraph (1)—*

1                   (A) by striking “subsection (i)” and insert-  
2                   ing “subsection (j)”; and

3                   (B) by striking at the end “or”;

4                   (2) by striking the period at the end of para-  
5                   graph (2) and inserting “; or”;

6                   (3) by inserting after paragraph (2) the follow-  
7                   ing:

8                   “(3) in the case of a food additive as defined in  
9                   this Act that is a food contact substance, there is—

10                   “(A) in effect, and such substance and the  
11                   use of such substance are in conformity with, a  
12                   regulation issued under this section prescribing  
13                   the conditions under which such additive may be  
14                   safely used; or

15                   “(B) a notification submitted under sub-  
16                   section (h) that is effective.”; and

17                   (4) by striking the matter following paragraph  
18                   (3) (as added by paragraph (2)) and inserting the fol-  
19                   lowing flush sentence:

20                   “While such a regulation relating to a food additive, or such  
21                   a notification under subsection (h) relating to a food addi-  
22                   tive that is a food contact substance, is in effect, and has  
23                   not been revoked pursuant to subsection (i), a food shall  
24                   not, by reason of bearing or containing such a food additive

1 *in accordance with the regulation or notification, be consid-*  
 2 *ered adulterated under section 402(a)(1).”.*

3 (b) *NOTIFICATION FOR FOOD CONTACT SUB-*  
 4 *STANCES.—Section 409 (21 U.S.C. 348), as amended by*  
 5 *subsection (a), is further amended—*

6 (1) *by redesignating subsections (h) and (i), as*  
 7 *subsections (i) and (j), respectively;*

8 (2) *by inserting after subsection (g) the follow-*  
 9 *ing:*

10 *“Notification Relating to a Food Contact Substance*

11 *“(h)(1) Subject to such regulations as may be promul-*  
 12 *gated under paragraph (3), a manufacturer or supplier of*  
 13 *a food contact substance may, at least 120 days prior to*  
 14 *the introduction or delivery for introduction into interstate*  
 15 *commerce of the food contact substance, notify the Secretary*  
 16 *of the identity and intended use of the food contact sub-*  
 17 *stance, and of the determination of the manufacturer or*  
 18 *supplier that the intended use of such food contact substance*  
 19 *is safe under the standard described in subsection (c)(3)(A).*  
 20 *The notification shall contain the information that forms*  
 21 *the basis of the determination, the fee required under para-*  
 22 *graph (5), and all information required to be submitted by*  
 23 *regulations promulgated by the Secretary.*

24 *“(2)(A) A notification submitted under paragraph (1)*  
 25 *shall become effective 120 days after the date of receipt by*

1 *the Secretary and the food contact substance may be intro-*  
2 *duced or delivered for introduction into interstate com-*  
3 *merce, unless the Secretary makes a determination within*  
4 *the 120-day period that, based on the data and information*  
5 *before the Secretary, such use of the food contact substance*  
6 *has not been shown to be safe under the standard described*  
7 *in subsection (c)(3)(A), and informs the manufacturer or*  
8 *supplier of such determination.*

9       “(B) *A decision by the Secretary to object to a notifica-*  
10 *tion shall constitute final agency action subject to judicial*  
11 *review.*

12       “(C) *In this paragraph, the term ‘food contact sub-*  
13 *stance’ means the substance that is the subject of a notifica-*  
14 *tion submitted under paragraph (1), and does not include*  
15 *a similar or identical substance manufactured or prepared*  
16 *by a person other than the manufacturer identified in the*  
17 *notification.*

18       “(3)(A) *The process in this subsection shall be utilized*  
19 *for authorizing the marketing of a food contact substance*  
20 *except where the Secretary determines that submission and*  
21 *review of a petition under subsection (b) is necessary to pro-*  
22 *vide adequate assurance of safety, or where the Secretary*  
23 *and any manufacturer or supplier agree that such manu-*  
24 *facturer or supplier may submit a petition under subsection*  
25 *(b).*

1       “(B) The Secretary is authorized to promulgate regu-  
2     lations to identify the circumstances in which a petition  
3     shall be filed under subsection (b), and shall consider cri-  
4     teria such as the probable consumption of such food contact  
5     substance and potential toxicity of the food contact sub-  
6     stance in determining the circumstances in which a petition  
7     shall be filed under subsection (b).

8       “(4) The Secretary shall keep confidential any infor-  
9     mation provided in a notification under paragraph (1) for  
10    120 days after receipt by the Secretary of the notification.  
11    After the expiration of such 120 days, the information shall  
12    be available to any interested party except for any matter  
13    in the notification that is a trade secret or confidential com-  
14    mercial information.

15       “(5)(A) Each person that submits a notification re-  
16    garding a food contact substance under this section shall  
17    be subject to the payment of a reasonable fee. The fee shall  
18    be based on the resources required to process the notification  
19    including reasonable administrative costs for such process-  
20    ing.

21       “(B) The Secretary shall conduct a study of the costs  
22    of administering the notification program established under  
23    this section and, on the basis of the results of such study,  
24    shall, within 18 months after the date of enactment of the  
25    Food and Drug Administration Modernization and Ac-

1 *countability Act of 1997, promulgate regulations establish-*  
 2 *ing the fee required by subparagraph (A).*

3       “(C) *A notification submitted without the appropriate*  
 4 *fee is not complete and shall not become effective for the*  
 5 *purposes of subsection (a)(3) until the appropriate fee is*  
 6 *paid.*

7       “(D) *Fees collected pursuant to this subsection—*

8               “(i) *shall not be deposited as an offsetting collec-*  
 9 *tion to the appropriations for the Department of*  
 10 *Health and Human Services;*

11              “(ii) *shall be credited to the appropriate account*  
 12 *of the Food and Drug Administration; and*

13              “(iii) *shall be available in accordance with ap-*  
 14 *propriation Acts until expended, without fiscal year*  
 15 *limitation.*

16       “(6) *In this section, the term ‘food contact substance’*  
 17 *means any substance intended for use as a component of*  
 18 *materials used in manufacturing, packing, packaging,*  
 19 *transporting, or holding food if such use is not intended*  
 20 *to have any technical effect in such food.”;*

21              (3) *in subsection (i), as so redesignated by para-*  
 22 *graph (1), by adding at the end the following: “The*  
 23 *Secretary shall by regulation prescribe the procedure*  
 24 *by which the Secretary may deem a notification*  
 25 *under subsection (h) to no longer be effective.”; and*

1           (4) in subsection (j), as so redesignated by para-  
 2           graph (1), by striking “subsections (b) to (h)” and in-  
 3           serting “subsections (b) to (i)”.

4           (c) *EFFECTIVE DATE*.—Notifications under section  
 5           409(h) of the Federal Food, Drug, and Cosmetic Act, as  
 6           added by subsection (b), may be submitted beginning 18  
 7           months after the date of enactment of this Act.

8           **SEC. 617. HEALTH CLAIMS FOR FOOD PRODUCTS.**

9           Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by  
 10          adding at the end the following:

11          “(C) Notwithstanding the provisions of clauses (A)(i)  
 12          and (B), a claim of the type described in subparagraph  
 13          (1)(B) that is not authorized by the Secretary in a regula-  
 14          tion promulgated in accordance with clause (B) shall be  
 15          authorized and may be made if—

16               “(i) an authoritative scientific body of the Fed-  
 17          eral Government with official responsibility for public  
 18          health protection or research directly relating to  
 19          human nutrition (such as the National Institutes of  
 20          Health or the Centers for Disease Control and Preven-  
 21          tion), the National Academy of Sciences, or a subdivi-  
 22          sion of the scientific body or the National Academy  
 23          of Sciences, has published an authoritative statement,  
 24          which is currently in effect, about the relationship be-



1        *tween a nutrient and a disease or health-related con-*  
 2        *dition to which the claim refers;*

3                *“(ii) a person has submitted to the Secretary at*  
 4        *least 90 days before the first introduction of a food*  
 5        *into interstate commerce a notice of the claim, includ-*  
 6        *ing a concise description of the basis upon which such*  
 7        *person relied for determining that the requirements of*  
 8        *subclause (i) have been satisfied;*

9                *“(iii) the claim and the food for which the claim*  
 10        *is made are in compliance with clause (A)(ii), and*  
 11        *are otherwise in compliance with paragraph (a) and*  
 12        *section 201(n); and*

13                *“(iv) the claim is stated in a manner so that the*  
 14        *claim is an accurate representation of the authori-*  
 15        *tative statement referred to in subclause (i) and so*  
 16        *that the claim enables the public to comprehend the*  
 17        *information provided in the claim and to understand*  
 18        *the relative significance of such information in the*  
 19        *context of a total daily diet.*

20        *For purposes of this paragraph, a statement shall be re-*  
 21        *garded as an authoritative statement of such a scientific*  
 22        *body described in subclause (i) only if the statement is pub-*  
 23        *lished by the scientific body and shall not include a state-*  
 24        *ment of an employee of the scientific body made in the indi-*  
 25        *vidual capacity of the employee.*

1       “(D) A claim meeting the requirements of clause (C)  
2 may be made until—

3               “(i) such time as the Secretary issues a final reg-  
4 ulation under clause (B) prohibiting or modifying the  
5 claim, and the regulation has become effective; or

6               “(ii) a district court of the United States in an  
7 enforcement proceeding under chapter III has deter-  
8 mined that the requirements of clause (C) have not  
9 been met.”.

10 **SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.**

11       Chapter V of the Federal Food, Drug, and Cosmetic  
12 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
13 section 505 the following:

14 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

15       “(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If,  
16 prior to approval of an application that is submitted under  
17 section 505(b)(1) the Secretary determines that information  
18 relating to the use of a drug in the pediatric population  
19 may produce health benefits in that population, the Sec-  
20 retary makes a written request for pediatric studies (which  
21 may include a timeframe for completing such studies), and  
22 such studies are completed within any such timeframe and  
23 the reports thereof submitted in accordance with subsection  
24 (d)(2) or completed within any such timeframe and the re-

1 *ports thereof are accepted in accordance with subsection*  
 2 *(d)(3)—*

3           “(1)(A) *the period during which an application*  
 4           *may not be submitted under subsections (c)(3)(D)(ii)*  
 5           *and (j)(4)(D)(ii) of section 505 shall be five years and*  
 6           *six months rather than five years, and the references*  
 7           *in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of sec-*  
 8           *tion 505 to four years, to forty-eight months, and to*  
 9           *seven and one-half years shall be deemed to be four*  
 10           *and one-half years, fifty-four months, and eight years,*  
 11           *respectively; or*

12           “(B) *the period of market exclusivity under sub-*  
 13           *sections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)*  
 14           *and (iv) of section 505 shall be three years and six*  
 15           *months rather than three years; and*

16           “(2)(A) *if the drug is the subject of—*

17                   “(i) *a listed patent for which a certification*  
 18                   *has been submitted under section*  
 19                   *505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and*  
 20                   *for which pediatric studies were submitted prior*  
 21                   *to the expiration of the patent (including any*  
 22                   *patent extensions); or*

23                   “(ii) *a listed patent for which a certifi-*  
 24                   *cation has been submitted under section*

1           505(b)(2)(A)(iii)                           or                           section  
 2           505(j)(2)(A)(vii)(III),  
 3       *the period during which an application may not be*  
 4       *approved under section 505(c)(3) or section*  
 5       *505(j)(4)(B) shall be extended by a period of six*  
 6       *months after the date the patent expires (including*  
 7       *any patent extensions); or*

8           “(B) *if the drug is the subject of a listed patent*  
 9       *for which a certification has been sub-*  
 10       *mitted under section 505(b)(2)(A)(iv) or section*  
 11       *505(j)(2)(A)(vii)(IV), and in the patent infringement*  
 12       *litigation resulting from the certification the court de-*  
 13       *termines that the patent is valid and would be in-*  
 14       *fringed, the period during which an application may*  
 15       *not be approved under section 505(c)(3) or section*  
 16       *505(j)(4)(B) shall be extended by a period of six*  
 17       *months after the date the patent expires (including*  
 18       *any patent extensions).*

19       “(b) *SECRETARY TO DEVELOP LIST OF DRUGS FOR*  
 20       *WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE*  
 21       *BENEFICIAL.—Not later than 180 days after the date of en-*  
 22       *actment of this section, the Secretary, after consultation*  
 23       *with experts in pediatric research (such as the American*  
 24       *Academy of Pediatrics, the Pediatric Pharmacology Re-*  
 25       *search Unit Network, and the United States Pharma-*

1 copoeia) shall develop, prioritize, and publish an initial list  
 2 of approved drugs for which additional pediatric informa-  
 3 tion may produce health benefits in the pediatric popu-  
 4 lation. The Secretary shall annually update the list.

5 “(c) *MARKET EXCLUSIVITY FOR ALREADY-MARKETED*  
 6 *DRUGS.*—If the Secretary makes a written request for pedi-  
 7 atric studies (which may include a timeframe for complet-  
 8 ing such studies) concerning a drug identified in the list  
 9 described in subsection (b) to the holder of an approved ap-  
 10 plication under section 505(b)(1) for the drug, the holder  
 11 agrees to the request, and the studies are completed within  
 12 any such timeframe and the reports thereof submitted in  
 13 accordance with subsection (d)(2) or completed within any  
 14 such timeframe and the reports thereof accepted in accord-  
 15 ance with subsection (d)(3)—

16 “(1)(A) the period during which an application  
 17 may not be submitted under subsections (c)(3)(D)(ii)  
 18 and (j)(4)(D)(ii) of section 505 shall be five years and  
 19 six months rather than five years, and the references  
 20 in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of sec-  
 21 tion 505 to four years, to forty-eight months, and to  
 22 seven and one-half years shall be deemed to be four  
 23 and one-half years, fifty-four months, and eight years,  
 24 respectively; or

1           “(B) the period of market exclusivity under sub-  
 2       sections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)  
 3       and (iv) of section 505 shall be three years and six  
 4       months rather than three years; and

5           “(2)(A) if the drug is the subject of—

6           “(i) a listed patent for which a certification  
 7       has been submitted under section  
 8       505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II) and for  
 9       which pediatric studies were submitted prior to  
 10      the expiration of the patent (including any pat-  
 11      ent extensions); or

12          “(ii) a listed patent for which a certifi-  
 13      cation has been submitted under section  
 14      505(b)(2)(A)(iii) or section  
 15      505(j)(2)(A)(vii)(III),

16      the period during which an application may not be  
 17      approved under section 505(c)(3) or section  
 18      505(j)(4)(B) shall be extended by a period of six  
 19      months after the date the patent expires (including  
 20      any patent extensions); or

21          “(B) if the drug is the subject of a listed patent  
 22      for which a certification has been submitted under  
 23      section 505(b)(2)(A)(iv) or section  
 24      505(j)(2)(A)(vii)(IV), and in the patent infringement  
 25      litigation resulting from the certification the court de-

1 *termines that the patent is valid and would be in-*  
 2 *fringed, the period during which an application may*  
 3 *not be approved under section 505(c)(3) or section*  
 4 *505(j)(4)(B) shall be extended by a period of six*  
 5 *months after the date the patent expires (including*  
 6 *any patent extensions).*

7 *“(d) CONDUCT OF PEDIATRIC STUDIES.—*

8 *“(1) AGREEMENT FOR STUDIES.—The Secretary*  
 9 *may, pursuant to a written request for studies, after*  
 10 *consultation with—*

11 *“(A) the sponsor of an application for an*  
 12 *investigational new drug under section 505(i);*

13 *“(B) the sponsor of an application for a*  
 14 *drug under section 505(b)(1); or*

15 *“(C) the holder of an approved application*  
 16 *for a drug under section 505(b)(1),*  
 17 *agree with the sponsor or holder for the conduct of pe-*  
 18 *diatric studies for such drug.*

19 *“(2) WRITTEN PROTOCOLS TO MEET THE STUD-*  
 20 *IES REQUIREMENT.—If the sponsor or holder and the*  
 21 *Secretary agree upon written protocols for the studies,*  
 22 *the studies requirement of subsection (a) or (c) is sat-*  
 23 *isfied upon the completion of the studies and submis-*  
 24 *sion of the reports thereof in accordance with the*  
 25 *original written request and the written agreement re-*

1       ferred to in paragraph (1). Not later than 60 days  
2       after the submission of the report of the studies, the  
3       Secretary shall determine if such studies were or were  
4       not conducted in accordance with the original written  
5       request and the written agreement and reported in ac-  
6       cordance with the requirements of the Secretary for  
7       filing and so notify the sponsor or holder.

8               “(3) OTHER METHODS TO MEET THE STUDIES  
9       REQUIREMENT.—If the sponsor or holder and the Sec-  
10      retary have not agreed in writing on the protocols for  
11      the studies, the studies requirement of subsection (a)  
12      or (c) is satisfied when such studies have been com-  
13      pleted and the reports accepted by the Secretary. Not  
14      later than 90 days after the submission of the reports  
15      of the studies, the Secretary shall accept or reject such  
16      reports and so notify the sponsor or holder. The Sec-  
17      retary’s only responsibility in accepting or rejecting  
18      the reports shall be to determine, within the 90 days,  
19      whether the studies fairly respond to the written re-  
20      quest, whether such studies have been conducted in ac-  
21      cordance with commonly accepted scientific principles  
22      and protocols, and whether such studies have been re-  
23      ported in accordance with the requirements of the  
24      Secretary for filing.



1       “(e) *DELAY OF EFFECTIVE DATE FOR CERTAIN APPLI-*  
2 *CATIONS; PERIOD OF MARKET EXCLUSIVITY.*—*If the Sec-*  
3 *retary determines that the acceptance or approval of an ap-*  
4 *plication under section 505(b)(2) or 505(j) for a drug may*  
5 *occur after submission of reports of pediatric studies under*  
6 *this section, which were submitted prior to the expiration*  
7 *of the patent (including any patent extension) or market*  
8 *exclusivity protection, but before the Secretary has deter-*  
9 *mined whether the requirements of subsection (d) have been*  
10 *satisfied, the Secretary shall delay the acceptance or ap-*  
11 *proval under section 505(b)(2) or 505(j), respectively, until*  
12 *the determination under subsection (d) is made, but such*  
13 *delay shall not exceed 90 days. In the event that require-*  
14 *ments of this section are satisfied, the applicable period of*  
15 *market exclusivity referred to in subsection (a) or (c) shall*  
16 *be deemed to have been running during the period of delay.*

17       “(f) *NOTICE OF DETERMINATIONS ON STUDIES RE-*  
18 *QUIREMENT.*—*The Secretary shall publish a notice of any*  
19 *determination that the requirements of subsection (d) have*  
20 *been met and that submissions and approvals under section*  
21 *505(b)(2) or (j) for a drug will be subject to the provisions*  
22 *of this section.*

23       “(g) *DEFINITIONS.*—*As used in this section, the term*  
24 *‘pediatric studies’ or ‘studies’ means at least 1 clinical in-*  
25 *vestigation (that, at the Secretary’s discretion, may include*

1 *pharmacokinetic studies) in pediatric age-groups in which*  
2 *a drug is anticipated to be used.*

3       “(h) *LIMITATION.*—*The holder of an approved applica-*  
4 *tion for a new drug that has already received six months*  
5 *of market exclusivity under subsection (a) or (c) may, if*  
6 *otherwise eligible, obtain six months of market exclusivity*  
7 *under subsection (c)(1)(B) for a supplemental application,*  
8 *except that the holder is not eligible for exclusivity under*  
9 *subsection (c)(2).*

10       “(i) *SUNSET.*—*No period of market exclusivity shall*  
11 *be granted under this section based on studies commenced*  
12 *after January 1, 2004. The Secretary shall conduct a study*  
13 *and report to Congress not later than January 1, 2003*  
14 *based on the experience under the program. The study and*  
15 *report shall examine all relevant issues, including—*

16               “(1) *the effectiveness of the program in improv-*  
17 *ing information about important pediatric uses for*  
18 *approved drugs;*

19               “(2) *the adequacy of the incentive provided*  
20 *under this section;*

21               “(3) *the economic impact of the program; and*

22               “(4) *any suggestions for modification that the*  
23 *Secretary deems appropriate.”.*

1 **SEC. 619. POSITRON EMISSION TOMOGRAPHY.**

2       (a) *REGULATION OF COMPOUNDED POSITRON EMIS-*  
 3 *SION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD,*  
 4 *DRUG, AND COSMETIC ACT.—*

5           (1) *DEFINITION.—Section 201 (21 U.S.C. 321),*  
 6 *as amended by section 405, is further amended by*  
 7 *adding at the end the following:*

8       “(jj) *The term ‘compounded positron emission tomog-*  
 9 *raphy drug’ means a drug that—*

10           “(1) *exhibits spontaneous disintegration of un-*  
 11 *stable nuclei, including the emission of positrons;*

12           “(2) *includes any nonradioactive reagent, rea-*  
 13 *gent kit, ingredient, nuclide generator, accelerator,*  
 14 *target material, electronic synthesizer, or other appa-*  
 15 *ratus or computer program to be used in the prepara-*  
 16 *tion of any such drug; and*

17           “(3)(A) *has been compounded in a State in ac-*  
 18 *cordance with State law for a patient or for research,*  
 19 *teaching, or quality control by or on the order of a*  
 20 *practitioner licensed by that State to compound or*  
 21 *order such a drug; or*

22           “(B) *has been compounded in a Federal facility*  
 23 *in a State in accordance with the law of the State in*  
 24 *which the facility is located.”.*

25       (b) *REGULATION AS A DRUG.—Section 501(a)(2) (21*  
 26 *U.S.C. 351(a)(2)) is amended by striking “; or (3)” and*

1 inserting the following: “; or (C) if it is a compounded  
 2 positron emission tomography drug and the methods used  
 3 in, or the facilities and controls used for, its compounding,  
 4 processing, packing, or holding do not conform to or are  
 5 not operated or administered in conformity with the  
 6 positron emission tomography compounding standards and  
 7 the official monographs of the United States Pharmacopoeia  
 8 to assure that such drug meets the requirements of this Act  
 9 as to safety and has the identity and strength, and meets  
 10 the quality and purity characteristics, which it purports  
 11 or is represented to possess; or (3)”.

12 (c) *REGULATION AS A NEW DRUG*.—Section 505 (21  
 13 U.S.C. 355) is amended by adding at the end the following:

14 “(n) The provisions of subsections (a) and (j) shall not  
 15 apply to the preparation of a compounded positron emis-  
 16 sion tomography drug.”.

17 (d) *REVOCATION OF CERTAIN INCONSISTENT DOCU-*  
 18 *MENTS*.—Not later than 30 days after the date of enactment  
 19 of this Act, the Secretary of Health and Human Services  
 20 shall publish in the Federal Register a notice revoking—

21 (1) a notice entitled “Regulation of Positron  
 22 Emission Tomographic Drug Products: Guidance;  
 23 Public Workshop”, published in the Federal Register  
 24 of February 27, 1995;

- 1           (2) a notice entitled “Guidance for Industry:  
2       *Current Good Manufacturing Practices for Positron*  
3       *Emission Tomographic (PET) Drug Products*”, pub-  
4       lished in the *Federal Register* of April 22, 1997; and  
5           (3) a final rule entitled “Current Good Manufac-  
6       turing Practice for Finished Pharmaceuticals;  
7       *Positron Emission Tomography*”, published in the  
8       *Federal Register* of April 22, 1997.

9       ***TITLE VII—FEES RELATING TO***  
10       ***DRUGS***

11   ***SEC. 701. SHORT TITLE.***

12       *This title may be cited as the “Prescription Drug User*  
13       *Fee Reauthorization Act of 1997”.*

14   ***SEC. 702. FINDINGS.***

15       *Congress finds that—*

16           (1) *prompt approval of safe and effective new*  
17       *drugs and other therapies is critical to the improve-*  
18       *ment of the public health so that patients may enjoy*  
19       *the benefits provided by these therapies to treat and*  
20       *prevent illness and disease;*

21           (2) *the public health will be served by making*  
22       *additional funds available for the purpose of aug-*  
23       *menting the resources of the Food and Drug Adminis-*  
24       *tration that are devoted to the process for review of*  
25       *human drug applications;*

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of \_\_\_\_\_, and \_\_\_\_\_, from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth at \_\_\_\_ Cong. Rec. \_\_\_\_\_ (daily ed. \_\_\_\_\_, 1997).

**SEC. 703. DEFINITIONS.**

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

1           (A) by striking “Service Act, and” and in-  
2           serting “Service Act,”; and

3           (B) by striking “September 1, 1992.” and  
4           inserting the following: “September 1, 1992, does  
5           not include an application for a licensure of a  
6           biological product for further manufacturing use  
7           only, and does not include an application or  
8           supplement submitted by a State or Federal Gov-  
9           ernment entity for a drug or biological product  
10          that is not distributed commercially. Such term  
11          does include an application for licensure, as de-  
12          scribed in subparagraph (D), of a large volume  
13          biological product intended for single dose injec-  
14          tion for intravenous use or infusion.”;

15          (2) in the second sentence of paragraph (3)—

16               (A) by striking “Service Act, and” and in-  
17               serting “Service Act,”; and

18               (B) by striking “September 1, 1992.” and  
19               inserting the following: “September 1, 1992, does  
20               not include a biological product that is licensed  
21               for further manufacturing use only, and does not  
22               include a drug or biological product that is not  
23               distributed commercially and is the subject of an  
24               application or supplement submitted by a State  
25               or Federal Government entity. Such term does

1       *include a large volume biological product in-*  
 2       *tended for single dose injection for intravenous*  
 3       *use or infusion.”;*

4       (3) in paragraph (4), by striking “without” and  
 5       inserting “without substantial”;

6       (4) in paragraph (7)(A)—

7               (A) by striking “employees under contract”  
 8               and all that follows through “Administration,”  
 9               and inserting “contractors of the Food and Drug  
 10              Administration,”; and

11             (B) by striking “and committees,” and in-  
 12             serting “and committees and to contracts with  
 13             such contractors,”;

14       (5) in paragraph (8)—

15             (A) in subparagraph (A)—

16               (i) by striking “August of” and insert-  
 17               ing “April of”; and

18               (ii) by striking “August 1992” and in-  
 19               serting “April 1997”;

20       (B) by striking subparagraph (B) and in-  
 21       serting the following:

22             “(B) 1 plus the total percentage increase for  
 23             such fiscal year since fiscal year 1997 in basic  
 24             pay under the General Schedule in accordance  
 25             with section 5332 of title 5, United States Code,



1       *as adjusted by any locality-based comparability*  
 2       *payment pursuant to section 5304 of such title*  
 3       *for Federal employees stationed in the District of*  
 4       *Columbia.”; and*

5               *(C) by striking the second sentence; and*

6       *(6) by adding at the end the following:*

7               *“(9) The term ‘affiliate’ means a business entity*  
 8       *that has a relationship with a second business entity*  
 9       *if, directly or indirectly—*

10              *“(A) 1 business entity controls, or has the*  
 11              *power to control, the other business entity; or*

12              *“(B) a third party controls, or has power to*  
 13              *control both of the business entities.”.*

14   **SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.**

15       *(a) TYPES OF FEES.—Section 736(a) (21 U.S.C.*  
 16       *379h(a)) is amended—*

17              *(1) by striking “Beginning in fiscal year 1993”*  
 18       *and inserting “Beginning in fiscal year 1998”;*

19              *(2) in paragraph (1)—*

20              *(A) by striking subparagraph (B) and in-*  
 21       *serting the following:*

22              *“(B) PAYMENT.—The fee required by sub-*  
 23       *paragraph (A) shall be due upon submission of*  
 24       *the application or supplement.”;*

25              *(B) in subparagraph (D)—*

1           (i) in the subparagraph heading, by  
 2           striking “NOT ACCEPTED” and inserting  
 3           “REFUSED”;

4           (ii) by striking “50 percent” and in-  
 5           serting “75 percent”;

6           (iii) by striking “subparagraph (B)(i)”  
 7           and inserting “subparagraph (B)”; and

8           (iv) by striking “not accepted” and in-  
 9           serting “refused”; and

10          (C) by adding at the end the following:

11          “(E) EXCEPTION FOR DESIGNATED ORPHAN  
 12          DRUG OR INDICATION.—A person that submits a  
 13          human drug application for a prescription drug  
 14          product that has been designated as a drug for  
 15          a rare disease or condition pursuant to section  
 16          526, or a supplement proposing to include a new  
 17          indication for a rare disease or condition pursu-  
 18          ant to section 526, shall not be assessed a fee  
 19          under subparagraph (A), unless the human drug  
 20          application includes indications for other than  
 21          rare diseases or conditions.

22          “(F) EXCEPTION FOR APPLICATIONS AND  
 23          SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A  
 24          person that submits a human drug application  
 25          or supplement that includes an indication for

1           *use in pediatric populations shall be assessed a*  
 2           *fee under subparagraph (A) only if—*

3                     *“(i) the application is for initial ap-*  
 4                     *proval for use in a pediatric population; or*

5                     *“(ii) the application or supplement is*  
 6                     *for approval for use in pediatric and non-*  
 7                     *pediatric populations.*

8                     *“(G) REFUND OF FEE IF APPLICATION*  
 9                     *WITHDRAWN.—If an application or supplement*  
 10                    *is withdrawn after the application or supple-*  
 11                    *ment is filed, the Secretary may waive and re-*  
 12                    *fund the fee or a portion of the fee if no substan-*  
 13                    *tial work was performed on the application or*  
 14                    *supplement after the application or supplement*  
 15                    *was filed. The Secretary shall have the sole dis-*  
 16                    *cretion to waive and refund a fee or a portion*  
 17                    *of the fee under this subparagraph. A determina-*  
 18                    *tion by the Secretary concerning a waiver or re-*  
 19                    *fund under this paragraph shall not be*  
 20                    *reviewable.”;*

21                    *(3) in paragraph (2)(A), by striking “505(j),*  
 22                    *and” and inserting the following: “505(j) or under an*  
 23                    *abbreviated new drug application pursuant to regula-*  
 24                    *tions in effect prior to the implementation of the*  
 25                    *Drug Price Competition and Patent Term Restora-*

1        *tion Act of 1984, or a product approved under an ap-*  
 2        *plication filed under section 507 that is abbreviated,*  
 3        *and”; and*

4            *(4) in paragraph (3)—*

5                    *(A) in subparagraph (A)—*

6                            *(i) in clause (i), by striking “is listed”*  
 7                            *and inserting “has been submitted for list-*  
 8                            *ing”; and*

9                            *(ii) by striking “Such fee shall be pay-*  
 10                            *able” and all that follows through “section*  
 11                            *510.” and inserting the following: “Such fee*  
 12                            *shall be payable for the fiscal year in which*  
 13                            *the product is first submitted for listing*  
 14                            *under section 510, or for relisting under sec-*  
 15                            *tion 510 if the product has been withdrawn*  
 16                            *from listing and relisted. After such fee is*  
 17                            *paid for that fiscal year, such fee shall be*  
 18                            *payable on or before January 31 of each*  
 19                            *year. Such fee shall be paid only once for*  
 20                            *each product for a fiscal year in which the*  
 21                            *fee is payable.”; and*

22                    *(B) in subparagraph (B), by striking*  
 23                    *“505(j).” and inserting the following: “505(j), or*  
 24                    *under an abbreviated new drug application pur-*  
 25                    *suant to regulations in effect prior to the imple-*

1           *mentation of the Drug Price Competition and*  
 2           *Patent Term Restoration Act of 1984, or is a*  
 3           *product approved under an application filed*  
 4           *under section 507 that is abbreviated.”.*

5           **(b) FEE AMOUNTS.**—Section 736(b) (21 U.S.C.  
 6 379h(b)) is amended to read as follows:

7           **“(b) FEE AMOUNTS.**—*Except as provided in sub-*  
 8           *sections (c), (d), (f), and (g), the fees required under sub-*  
 9           *section (a) shall be determined and assessed as follows:*

10           **“(1) APPLICATION AND SUPPLEMENT FEES.**—

11                   **“(A) FULL FEES.**—*The application fee*  
 12                   *under subsection (a)(1)(A)(i) shall be \$250,704*  
 13                   *in fiscal year 1998, \$256,338 in each of fiscal*  
 14                   *years 1999 and 2000, \$267,606 in fiscal year*  
 15                   *2001, and \$258,451 in fiscal year 2002.*

16                   **“(B) OTHER FEES.**—*The fee under sub-*  
 17                   *section (a)(1)(A)(ii) shall be \$125,352 in fiscal*  
 18                   *year 1998, \$128,169 in each of fiscal years 1999*  
 19                   *and 2000, \$133,803 in fiscal year 2001, and*  
 20                   *\$129,226 in fiscal year 2002.*

21           **“(2) FEE REVENUES FOR ESTABLISHMENT**  
 22           **FEES.**—*The total fee revenues to be collected in estab-*  
 23           *lishment fees under subsection (a)(2) shall be*  
 24           *\$35,600,000 in fiscal year 1998, \$36,400,000 in each*

1       of fiscal years 1999 and 2000, \$38,000,000 in fiscal  
2       year 2001, and \$36,700,000 in fiscal year 2002.

3               “(3) *TOTAL FEE REVENUES FOR PRODUCT*  
4       *FEES.*—*The total fee revenues to be collected in prod-*  
5       *uct fees under subsection (a)(3) in a fiscal year shall*  
6       *be equal to the total fee revenues collected in establish-*  
7       *ment fees under subsection (a)(2) in that fiscal year.”.*

8       (c) *INCREASES AND ADJUSTMENTS.*—*Section 736(c)*  
9       *(21 U.S.C. 379h(c)) is amended—*

10           (1) *in the subsection heading, by striking “IN-*  
11       *CREASES AND”;*

12           (2) *in paragraph (1)—*

13               (A) *by striking “(1) REVENUE” and all that*  
14       *follows through “increased by the Secretary” and*  
15       *inserting the following: “(1) INFLATION ADJUST-*  
16       *MENT.*—*The fees and total fee revenues estab-*  
17       *lished in subsection (b) shall be adjusted by the*  
18       *Secretary”;*

19               (B) *in subparagraph (A), by striking “in-*  
20       *crease” and inserting “change”;*

21               (C) *in subparagraph (B), by striking “in-*  
22       *crease” and inserting “change”; and*

23               (D) *by adding at the end the following flush*  
24       *sentence:*

1       *“The adjustment made each fiscal year by this sub-*  
 2       *section will be added on a compounded basis to the*  
 3       *sum of all adjustments made each fiscal year after fis-*  
 4       *cal year 1997 under this subsection.”;*

5           (3) in paragraph (2), by striking *“October 1,*  
 6       *1992,”* and all that follows through *“such schedule.”*  
 7       and inserting the following: *“September 30, 1997, ad-*  
 8       *just the establishment and product fees described in*  
 9       *subsection (b) for the fiscal year in which the adjust-*  
 10       *ment occurs so that the revenues collected from each*  
 11       *of the categories of fees described in paragraphs (2)*  
 12       *and (3) of subsection (b) shall be set to be equal to*  
 13       *the revenues collected during the past fiscal year from*  
 14       *the category of application and supplement fees de-*  
 15       *scribed in paragraph (1) of subsection (b).”;* and

16           (4) in paragraph (3), by striking *“paragraph*  
 17       *(2)”* and inserting *“this subsection”*.

18       (d) *FEE WAIVER OR REDUCTION.—Section 736(d) (21*  
 19       *U.S.C. 379h(d)) is amended—*

20           (1) by redesignating paragraphs (1), (2), (3),  
 21       and (4) as subparagraphs (A), (B), (C), and (D), re-  
 22       spectively and indenting appropriately;

23           (2) by striking *“The Secretary shall grant a”*  
 24       and all that follows through *“finds that—”* and in-  
 25       serting the following:

1           “(1) *IN GENERAL.*—*The Secretary shall grant a*  
 2           *waiver from or a reduction of 1 or more fees assessed*  
 3           *under subsection (a) where the Secretary finds*  
 4           *that—*”;

5           (3) *in subparagraph (C) (as so redesignated by*  
 6           *paragraph (1)), by striking “, or” and inserting a*  
 7           *comma;*

8           (4) *in subparagraph (D) (as so redesignated by*  
 9           *paragraph (1)), by striking the period and inserting*  
 10          *“, or”;*

11          (5) *by inserting after subparagraph (D) (as so*  
 12          *redesignated by paragraph (1)) the following:*

13               “(E) *the applicant is a small business sub-*  
 14               *mitting its first human drug application to the*  
 15               *Secretary for review.*”; and

16          (6) *by striking “In making the finding in para-*  
 17          *graph (3),” and all that follows through “standard*  
 18          *costs.” and inserting the following:*

19               “(2) *USE OF STANDARD COSTS.*—*In making the*  
 20               *finding in paragraph (1)(C), the Secretary may use*  
 21               *standard costs.*

22               “(3) *RULES RELATING TO SMALL BUSINESSES.*—

23                       “(A) *DEFINITION.*—*In paragraph (1)(E),*  
 24                       *the term ‘small business’ means an entity that*



1       *has fewer than 500 employees, including employ-*  
 2       *ees of affiliates.*

3               “(B) *WAIVER OF APPLICATION FEE.*—*The*  
 4       *Secretary shall waive under paragraph (1)(E)*  
 5       *the application fee for the first human drug ap-*  
 6       *plication that a small business or its affiliate*  
 7       *submits to the Secretary for review. After a small*  
 8       *business or its affiliate is granted such a waiver,*  
 9       *the small business or its affiliate shall pay—*

10               “(i) *application fees for all subsequent*  
 11       *human drug applications submitted to the*  
 12       *Secretary for review in the same manner as*  
 13       *an entity that does not qualify as a small*  
 14       *business; and*

15               “(ii) *all supplement fees for all supple-*  
 16       *ments to human drug applications submit-*  
 17       *ted to the Secretary for review in the same*  
 18       *manner as an entity that does not qualify*  
 19       *as a small business.”.*

20       (e) *ASSESSMENT OF FEES.*—*Section 736(f)(1) (21*  
 21       *U.S.C. 379h(f)(1)) is amended—*

22               (1) *by striking “fiscal year 1993” and inserting*  
 23       *“fiscal year 1997”; and*

1           (2) by striking “fiscal year 1992” and inserting  
 2           “fiscal year 1997 (excluding the amount of fees ap-  
 3           propriated for such fiscal year)”.

4           (f) *CREDITING AND AVAILABILITY OF FEES.*—Section  
 5   736(g) (21 U.S.C. 379h(g)) is amended—

6           (1) in paragraph (1), by adding at the end the  
 7           following: “Such sums as may be necessary may be  
 8           transferred from the Food and Drug Administration  
 9           salaries and expenses appropriation account without  
 10          fiscal year limitation to such appropriation account  
 11          for salaries and expenses with such fiscal year limita-  
 12          tion. The sums transferred shall be available solely for  
 13          the process for the review of human drug applications  
 14          within the meaning of section 735(6).”;

15          (2) in paragraph (2)—

16                (A) in subparagraph (A), by striking  
 17                “Acts” and inserting “Acts, or otherwise made  
 18                available for obligation,”; and

19                (B) in subparagraph (B), by striking “over  
 20                such costs for fiscal year 1992” and inserting  
 21                “over such costs, excluding costs paid from fees  
 22                collected under this section, for fiscal year 1997”;  
 23                and

24           (3) by striking paragraph (3) and inserting the  
 25           following:

1           “(3) *AUTHORIZATION OF APPROPRIATIONS.*—

2           *There is authorized to be appropriated for fees under*  
 3           *this section—*

4                     “(A) \$106,800,000 for fiscal year 1998;

5                     “(B) \$109,200,000 for fiscal year 1999;

6                     “(C) \$109,200,000 for fiscal year 2000;

7                     “(D) \$114,000,000 for fiscal year 2001; and

8                     “(E) \$110,100,000 for fiscal year 2002,

9           *as adjusted to reflect adjustments in the total fee reve-*  
 10           *nuues made under this section and changes in the total*  
 11           *amounts collected by application, supplement, estab-*  
 12           *lishment, and product fees.*

13           “(4) *OFFSET.*—*Any amount of fees collected for*  
 14           *a fiscal year which exceeds the amount of fees speci-*  
 15           *fied in appropriation Acts for such fiscal year, shall*  
 16           *be credited to the appropriation account of the Food*  
 17           *and Drug Administration as provided in paragraph*  
 18           *(1), and shall be subtracted from the amount of fees*  
 19           *that would otherwise be authorized to be collected*  
 20           *under appropriation Acts for a subsequent fiscal*  
 21           *year.”.*

22           (g) *REQUIREMENT FOR WRITTEN REQUESTS FOR*  
 23           *WAIVERS, REDUCTIONS, AND FEES.*—*Section 736 (21*  
 24           *U.S.C. 379h) is amended—*

1           (1) *by redesignating subsection (i) as subsection*  
 2           *(j); and*

3           (2) *by inserting after subsection (h) the follow-*  
 4           *ing:*

5           “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*  
 6           *AND REFUNDS.—To qualify for consideration for a waiver*  
 7           *or reduction under subsection (d), or for a refund, of any*  
 8           *fee collected in accordance with subsection (a), a person*  
 9           *shall submit to the Secretary a written request for such*  
 10           *waiver, reduction, or refund not later than 180 days after*  
 11           *such fee is due.”.*

12           (h) *SPECIAL RULE FOR WAIVER, REFUNDS, AND EX-*  
 13           *CEPTIONS.—Any requests for waivers, refunds, or exceptions*  
 14           *for fees paid prior to the date of enactment of this Act shall*  
 15           *be submitted in writing to the Secretary of Health and*  
 16           *Human Services within 1 year after the date of enactment*  
 17           *of this Act.*

18   **SEC. 705. ANNUAL REPORTS.**

19           (a) *FIRST REPORT.—Beginning with fiscal year 1998,*  
 20           *not later than 60 days after the end of each fiscal year dur-*  
 21           *ing which fees are collected under part 2 of subchapter C*  
 22           *of chapter VII of the Federal Food, Drug, and Cosmetic Act*  
 23           *(21 U.S.C. 379g et seq.), the Secretary of Health and*  
 24           *Human Services shall prepare and submit to the Committee*  
 25           *on Commerce of the House of Representatives and the Com-*

1 *mittee on Labor and Human Resources of the Senate a re-*  
 2 *port concerning the progress of the Food and Drug Admin-*  
 3 *istration in achieving the goals identified in the letter de-*  
 4 *scribed in section 702(4) during such fiscal year and the*  
 5 *future plans of the Food and Drug Administration for meet-*  
 6 *ing the goals.*

7       (b) *SECOND REPORT.*—Beginning with fiscal year  
 8 1998, not later than 120 days after the end of each fiscal  
 9 year during which fees are collected under the part de-  
 10 scribed in subsection (a), the Secretary of Health and  
 11 Human Services shall prepare and submit to the Committee  
 12 on Commerce of the House of Representatives and the Com-  
 13 mittee on Labor and Human Resources of the Senate a re-  
 14 port on the implementation of the authority for such fees  
 15 during such fiscal year and the use, by the Food and Drug  
 16 Administration, of the fees collected during such fiscal year  
 17 for which the report is made.

18 **SEC. 706. EFFECTIVE DATE.**

19       *The amendments made by this title shall take effect*  
 20 *October 1, 1997.*

21 **SEC. 707. TERMINATION OF EFFECTIVENESS.**

22       *The amendments made by sections 703 and 704 cease*  
 23 *to be effective October 1, 2002 and section 705 ceases to be*  
 24 *effective 120 days after such date.*

1       ***TITLE VIII—MISCELLANEOUS***

2       ***SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.***

3           *Section 510(i) (21 U.S.C. 360(i)) is amended to read*  
4       *as follows:*

5           “(i)(1) *Any establishment within any foreign country*  
6       *engaged in the manufacture, preparation, propagation,*  
7       *compounding, or processing of a drug or a device that is*  
8       *imported or offered for import into the United States shall*  
9       *register with the Secretary the name and place of business*  
10       *of the establishment and the name of the United States*  
11       *agent for the establishment.*

12          “(2) *The establishment shall also provide the informa-*  
13       *tion required by subsection (j).*

14          “(3) *The Secretary is authorized to enter into coopera-*  
15       *tive arrangements with foreign countries to ensure that ade-*  
16       *quate and effective means are available for purposes of de-*  
17       *termining, from time to time, whether drugs or devices*  
18       *manufactured, prepared, propagated, compounded, or proc-*  
19       *essed by an establishment described in paragraph (1), if im-*  
20       *ported or offered for import into the United States, shall*  
21       *be refused admission on any of the grounds set forth in sec-*  
22       *tion 801(a).”.*

1 **SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIRE-**  
 2 **MENTS.**

3 (a) *PRESCRIPTION DRUGS.*—Section 503(b)(4) (21  
 4 U.S.C. 353(b)(4)) is amended to read as follows:

5 “(4)(A) A drug that is subject to paragraph (1) shall  
 6 be deemed to be misbranded if at any time prior to dispens-  
 7 ing the label of the drug fails to bear, at a minimum, the  
 8 symbol ‘Rx only’.

9 “(B) A drug to which paragraph (1) does not apply  
 10 shall be deemed to be misbranded if at any time prior to  
 11 dispensing the label of the drug bears the symbol described  
 12 in subparagraph (A).”.

13 (b) *MISBRANDED DRUG.*—Section 502(d) (21 U.S.C.  
 14 352(d)) is repealed.

15 (c) *CONFORMING AMENDMENTS.*—

16 (1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is  
 17 amended—

18 (A) by striking subparagraph (A); and

19 (B) by redesignating subparagraphs (B)  
 20 and (C) as subparagraphs (A) and (B), respec-  
 21 tively.

22 (2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is  
 23 amended by striking “section 502(d) and”.

24 (3) Section 102(9)(A) of the Controlled Sub-  
 25 stances Act (21 U.S.C. 802(9)(A)) is amended—

26 (A) in clause (i), by striking “(i)”; and

1                   (B) by striking “(ii)” and all that follows.

2   **SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.**

3       Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

4           (1) in paragraph (1), in the fifth sentence, by  
5       striking “paragraphs (1) and (2) of section 801(e)”  
6       and inserting “subparagraphs (A) and (B) of section  
7       801(e)(1)”; and

8           (2) by inserting after the fifth sentence the fol-  
9       lowing: “Any person seeking to export an imported  
10      article pursuant to any of the provisions of this sub-  
11      section shall establish that the article was intended for  
12      export at the time the article entered commerce.”.

13   **SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PRO-**  
14                   **GRAM.**

15      Chapter IX (21 U.S.C. 391 et seq.), as amended by  
16      section 203, is further amended by adding at the end the  
17      following:

18   **“SEC. 907. INTRAMURAL RESEARCH TRAINING AWARD PRO-**  
19                   **GRAM.**

20           “(a) *IN GENERAL.*—The Secretary, acting through the  
21      Commissioner of Food and Drugs, may, directly or through  
22      grants, contracts, or cooperative agreements, conduct and  
23      support intramural research training in regulatory sci-  
24      entific programs by predoctoral and postdoctoral scientists



1 *and physicians, including the support through the use of*  
 2 *fellowships.*

3 “(b) *LIMITATION ON PARTICIPATION.*—*A recipient of*  
 4 *a fellowship under subsection (a) may not be an employee*  
 5 *of the Federal Government.*

6 “(c) *SPECIAL RULE.*—*The Secretary, acting through*  
 7 *the Commissioner of Food and Drugs, may support the pro-*  
 8 *vision of assistance for fellowships described in subsection*  
 9 *(a) through a Cooperative Research and Development*  
 10 *Agreement.”.*

11 **SEC. 805. DEVICE SAMPLES.**

12 (a) *RECALL AUTHORITY.*—

13 (1) *IN GENERAL.*—*Section 518(e)(2) (21 U.S.C.*  
 14 *360h(e)(2)) is amended by adding at the end the fol-*  
 15 *lowing:*

16 “(C) *If the Secretary issues an amended order under*  
 17 *subparagraph (A), the Secretary may require the person*  
 18 *subject to the order to submit such samples of the device*  
 19 *and of components of the device as the Secretary may rea-*  
 20 *sonably require. If the submission of such samples is im-*  
 21 *practicable or unduly burdensome, the requirement of this*  
 22 *subparagraph may be met by the submission of complete*  
 23 *information concerning the location of 1 or more such de-*  
 24 *vices readily available for examination and testing.”.*

1           (2)        *TECHNICAL        AMENDMENT.—Section*  
 2        518(e)(2)(A) (21 U.S.C. 360h(e)(2)(A)) is amended by  
 3        striking “subparagraphs (B) and (C)” and inserting  
 4        “subparagraph (B)”.

5        (b) *RECORDS AND REPORTS ON DEVICES.—Section*  
 6        519(a) (21 U.S.C. 360i(a)) is amended by inserting after  
 7        paragraph (9) the following:

8           “(10) may reasonably require a manufacturer,  
 9        importer, or distributor to submit samples of a device  
 10       and of components of the device that may have caused  
 11       or contributed to a death or serious injury, except  
 12       that if the submission of such samples is impractica-  
 13       ble or unduly burdensome, the requirement of this  
 14       paragraph may be met by the submission of complete  
 15       information concerning the location of 1 or more such  
 16       devices readily available for examination and test-  
 17       ing.”.

18   **SEC. 806. INTERSTATE COMMERCE.**

19       Section 709 (21 U.S.C. 379a) is amended by striking  
 20       “a device” and inserting “a device, food, drug, or cosmetic”.

21   **SEC. 807. NATIONAL UNIFORMITY FOR NONPRESCRIPTION**  
 22       **DRUGS AND COSMETICS.**

23       Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 24       section 614, is further amended by adding at the end the  
 25       following:

1 “SUBCHAPTER F—NATIONAL UNIFORMITY FOR NON-  
 2 PRESCRIPTION DRUGS FOR HUMAN USE AND COS-  
 3 METICS

4 “SEC. 761. NATIONAL UNIFORMITY FOR NONPRESCRIPTION  
 5 DRUGS AND COSMETICS.

6 “(a) IN GENERAL.—Except as provided in subsection  
 7 (b), (c)(1), or (d), no State or political subdivision of a  
 8 State may establish or continue in effect any requirement—  
 9 “(1) that relates to the regulation of a drug in-  
 10 tended for human use that is not subject to the re-  
 11 quirements of section 503(b)(1) or a cosmetic; and

12 “(2) that is different from or in addition to, or  
 13 that is otherwise not identical with, a requirement of  
 14 this Act, the Poison Prevention Packaging Act of  
 15 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging  
 16 and Labeling Act (15 U.S.C. 1451 et seq.).

17 “(b) EXEMPTION.—Upon application of a State, the  
 18 Secretary may by regulation, after notice and opportunity  
 19 for written and oral presentation of views, exempt from sub-  
 20 section (a), under such condition as may be prescribed in  
 21 such regulation, a State requirement that—

22 “(1) protects an important public interest that  
 23 would otherwise be unprotected;

1           “(2) *would not cause any drug or cosmetic to be*  
2           *in violation of any applicable requirement or prohibi-*  
3           *tion under Federal law; and*

4           “(3) *would not unduly burden interstate com-*  
5           *merce.*

6           “(c) *SCOPE.—For purposes of subsection (a), a re-*  
7           *quirement that relates to the regulation of a drug or cos-*  
8           *metic—*

9           “(1) *shall not include any requirement that re-*  
10          *lates to the practice of pharmacy or any requirement*  
11          *that a drug be dispensed only upon the prescription*  
12          *of a practitioner licensed by law to administer such*  
13          *drug; and*

14          “(2) *shall be deemed to include any requirement*  
15          *relating to public information or any other form of*  
16          *public communication relating to the safety or effec-*  
17          *tiveness of a drug or cosmetic.*

18          “(d) *NO EFFECT ON PRODUCT LIABILITY LAW.—Noth-*  
19          *ing in this section shall be construed to modify or otherwise*  
20          *affect any action or the liability of any person under the*  
21          *product liability law of any State.”.*

1 **SEC. 808. INFORMATION PROGRAM ON CLINICAL TRIALS**  
2 **FOR SERIOUS OR LIFE-THREATENING DIS-**  
3 **EASES.**

4 (a) *IN GENERAL.*—Section 402 of the Public Health  
5 Service Act (42 U.S.C. 282) is amended—

6 (1) *by redesignating subsections (j) and (k) as*  
7 *subsections (k) and (l), respectively; and*

8 (2) *by inserting after subsection (i), the follow-*  
9 *ing:*

10 “(j)(1) *The Secretary, acting through the Director of*  
11 *the National Institutes of Health and subject to the avail-*  
12 *ability of appropriations, shall establish, maintain, and op-*  
13 *erate a program with respect to information on research*  
14 *relating to the treatment, detection, and prevention of seri-*  
15 *ous or life-threatening diseases and conditions. The pro-*  
16 *gram shall, with respect to the agencies of the Department*  
17 *of Health and Human Services, be integrated and coordi-*  
18 *nated, and, to the extent practicable, coordinated with other*  
19 *data banks containing similar information.*

20 “(2)(A) *After consultation with the Commissioner of*  
21 *Food and Drugs, the directors of the appropriate agencies*  
22 *of the National Institutes of Health (including the National*  
23 *Library of Medicine), and the Director of the Centers for*  
24 *Disease Control and Prevention, the Secretary shall, in car-*  
25 *rying out paragraph (1), establish a data bank of informa-*

1 *tion on clinical trials for drugs, and biologicals, for serious*  
 2 *or life-threatening diseases and conditions.*

3       “(B) *In carrying out subparagraph (A), the Secretary*  
 4 *shall collect, catalog, store and disseminate the information*  
 5 *described in such subparagraph. The Secretary shall dis-*  
 6 *seminate such information through information systems,*  
 7 *which shall include toll-free telephone communications,*  
 8 *available to individuals with serious or life-threatening dis-*  
 9 *eases and conditions, to other members of the public, to*  
 10 *health care providers, and to researchers.*

11       “(3) *The Data Bank shall include the following:*

12               “(A) *A registry of clinical trials (whether feder-*  
 13 *ally or privately funded) of experimental treatments*  
 14 *for serious or life-threatening diseases and conditions*  
 15 *under regulations promulgated pursuant to sections*  
 16 *505 and 520 of the Federal Food, Drug, and Cosmetic*  
 17 *Act that provides a description of the purpose of each*  
 18 *experimental drug or biological protocol, either with*  
 19 *the consent of the protocol sponsor, or when a trial to*  
 20 *test efficacy begins. Information provided shall consist*  
 21 *of eligibility criteria, a description of the location of*  
 22 *trial sites, and a point of contact for those wanting*  
 23 *to enroll in the trial, and shall be in a form that can*  
 24 *be readily understood by members of the public. Such*  
 25 *information must be forwarded to the Data Bank by*

1        *the sponsor of the trial not later than 21 days after*  
2        *the approval by the Food and Drug Administration.*

3            *“(B) Information pertaining to experimental*  
4        *treatments for serious or life-threatening diseases and*  
5        *conditions that may be available—*

6            *“(i) under a treatment investigational new*  
7        *drug application that has been submitted to the*  
8        *Food and Drug Administration pursuant to part*  
9        *312 of title 21, Code of Federal Regulations; or*

10        *“(ii) as a Group C cancer drug.*

11        *The Data Bank may also include information per-*  
12        *taining to the results of clinical trials of such treat-*  
13        *ments, with the consent of the sponsor, including in-*  
14        *formation concerning potential toxicities or adverse*  
15        *effects associated with the use or administration of*  
16        *such experimental treatments.*

17        *“(4) The Data Bank shall not include information re-*  
18        *lating to an investigation if the sponsor has certified to the*  
19        *Secretary that disclosure of such information would sub-*  
20        *stantially interfere with the timely enrollment of subjects*  
21        *in the investigation.*

22        *“(5) For the purpose of carrying out this subsection,*  
23        *there are authorized to be appropriated such sums as may*  
24        *be necessary. Fees collected under section 736 of the Federal*  
25        *Food, Drug, and Cosmetic (21 U.S.C. 379h) shall not be*

1 *authorized or appropriated for use in carrying out this sub-*  
2 *section.”.*

3 *(b) COLLABORATION AND REPORT.—*

4 *(1) IN GENERAL.—The Secretary of Health and*  
5 *Human Services, the Director of the National Insti-*  
6 *tutes of Health, and the Commissioner of Food and*  
7 *Drugs shall collaborate to determine the feasibility of*  
8 *including device investigations within the scope of the*  
9 *registry requirements set forth in subsection (j) of sec-*  
10 *tion 402 of the Public Health Service Act.*

11 *(2) REPORT.—Not later than 2 years after the*  
12 *date of enactment of this section, the Secretary of*  
13 *Health and Human Services shall prepare and sub-*  
14 *mit to the Committee on Labor and Human Re-*  
15 *sources of the Senate and the Committee on Commerce*  
16 *of the House of Representatives a report that shall*  
17 *consider, among other things—*

18 *(A) the public health need, if any, for inclu-*  
19 *sion of device investigations within the scope of*  
20 *the registry requirements set forth in subsection*  
21 *(j) of section 402 of the Public Health Service*  
22 *Act; and*

23 *(B) the adverse impact, if any, on device*  
24 *innovation and research in the United States if*



1           *information relating to such device investiga-*  
 2           *tions is required to be publicly disclosed.*

3   **SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRAC-**  
 4           **TICE OF PHARMACY COMPOUNDING.**

5           *Section 503 (21 U.S.C. 353) is amended by adding*  
 6   *at the end the following:*

7           “(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505,  
 8   *and 507 shall not apply to a drug product if—*

9           “(A) *the drug product is compounded for an*  
 10          *identified individual patient, based on a medical need*  
 11          *for a compounded product—*

12               “(i) *by a licensed pharmacist in a State li-*  
 13               *censed pharmacy or a Federal facility, or a li-*  
 14               *censed physician, on the prescription order of a*  
 15               *licensed physician or other licensed practitioner*  
 16               *authorized by State law to prescribe drugs; or*

17               “(ii) *by a licensed pharmacist or licensed*  
 18               *physician in limited quantities, prior to the re-*  
 19               *ceipt of a valid prescription order for the identi-*  
 20               *fied individual patient, and is compounded*  
 21               *based on a history of the licensed pharmacist or*  
 22               *licensed physician receiving valid prescription*  
 23               *orders for the compounding of the drug product*  
 24               *that have been generated solely within an estab-*

1           *lished relationship between the licensed phar-*  
2           *macist, or licensed physician, and—*

3                   “(I) *the individual patient for whom*  
4                   *the prescription order will be provided; or*

5                   “(II) *the physician or other licensed*  
6                   *practitioner who will write such prescrip-*  
7                   *tion order; and*

8                   “(B) *the licensed pharmacist or licensed physi-*  
9                   *cian—*

10                   “(i) *compounds the drug product using bulk*  
11                   *drug substances—*

12                   “(I) *that—*

13                           “(aa) *comply with the standards*  
14                           *of an applicable United States Phar-*  
15                           *macopeia monograph; or*

16                           “(bb) *in a case in which such a*  
17                           *monograph does not exist, are drug*  
18                           *substances that are covered by regula-*  
19                           *tions issued by the Secretary under*  
20                           *paragraph (3);*

21                   “(II) *that are manufactured by an es-*  
22                   *tablishment that is registered under section*  
23                   *510 (including a foreign establishment that*  
24                   *is registered under section 510(i)); and*

1                   “(III) that are accompanied by valid  
2                   certificates of analysis for each bulk drug  
3                   substance;

4                   “(ii) compounds the drug product using in-  
5                   gredients (other than bulk drug substances) that  
6                   comply with the standards of an applicable  
7                   United States Pharmacopeia monograph and the  
8                   United States Pharmacopeia chapter on phar-  
9                   macy compounding;

10                  “(iii) only advertises or promotes the  
11                  compounding service provided by the licensed  
12                  pharmacist or licensed physician and does not  
13                  advertise or promote the compounding of any  
14                  particular drug, class of drug, or type of drug;

15                  “(iv) does not compound a drug product  
16                  that appears on a list published by the Secretary  
17                  in the Federal Register of drug products that  
18                  have been withdrawn or removed from the mar-  
19                  ket because such drug products or components of  
20                  such drug products have been found to be unsafe  
21                  or not effective;

22                  “(v) does not compound a drug product that  
23                  is identified by the Secretary in regulation as  
24                  presenting demonstrable difficulties for  
25                  compounding that reasonably demonstrate an

1       *adverse effect on the safety or effectiveness of that*  
2       *drug product; and*

3               “(vi) *does not distribute compounded drugs*  
4       *outside of the State in which the drugs are*  
5       *compounded, unless the principal State agency*  
6       *of jurisdiction that regulates the practice of*  
7       *pharmacy in such State has entered into a*  
8       *memorandum of understanding with the Sec-*  
9       *retary (based on the adequate regulation of*  
10       *compounding performed in the State) that pro-*  
11       *vides for appropriate investigation by the State*  
12       *agency of complaints relating to compounded*  
13       *products distributed outside of the State.*

14       “(2)(A) *The Secretary shall, after consultation with*  
15       *the National Association of Boards of Pharmacy, develop*  
16       *a standard memorandum of understanding for use by*  
17       *States in complying with paragraph (1)(B)(vi).*

18       “(B) *Paragraph (1)(B)(vi) shall not apply to a li-*  
19       *censed pharmacist or licensed physician, who does not dis-*  
20       *tribute inordinate amounts of compounded products outside*  
21       *of the State, until—*

22               “(i) *the date that is 180 days after the develop-*  
23       *ment of the standard memorandum of understanding;*  
24       *or*

1           “(ii) the date on which the State agency enters  
2       into a memorandum of understanding under para-  
3       graph (1)(B)(vi),  
4       whichever occurs first.

5           “(3) The Secretary, after consultation with the United  
6       States Pharmacopeia Convention Incorporated, shall pro-  
7       mulgate regulations limiting compounding under para-  
8       graph (1)(B)(i)(I)(bb) to drug substances that are compo-  
9       nents of drug products approved by the Secretary and to  
10      other drug substances as the Secretary may identify.

11          “(4) The provisions of paragraph (1) shall not apply—

12               “(A) to compounded positron emission tomog-  
13       raphy drugs as defined in section 202(jj); or

14               “(B) to radiopharmaceuticals.”.